

The Board of Directors and the Chief Executive Officer of

**Biovitrum AB (publ)**

Corporate Identity no. 556038-9321

hereby submit

**Annual Report  
and  
Consolidated Financial Statements**

for the financial year

**January 1 – December 31  
2009**

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## Directors' report

(Refers to both the Group and parent company, as applicable)

### General information on operations

Biovitrum is an international pharmaceuticals company that markets specialist pharmaceuticals in several regions. Biovitrum focuses on development and production of biopharmaceuticals within our prioritized areas of hemophilia, inflammation/autoimmune diseases, cancer supportive care and fat malabsorption. In 2009 Biovitrum had net sales of SEK 1.3 billion and 380 employees at the end of the year.

Biovitrum's mission is to develop and sell specialist pharmaceuticals that improve people's lives. The business goal is to be a pharmaceutical company with long-term profitability.

Biovitrum develops its portfolio of specialist care projects internally or with partners to be able to generate future revenues.

In 2009 the company generated revenues through:

- Production of the active pharmaceutical substance for ReFacto<sup>®</sup>, royalties from Pfizer's global sales of ReFacto<sup>®</sup> and co-promotion revenues from the sale of ReFacto<sup>®</sup> in the Nordic region.
- Sales of Kineret<sup>®</sup>, Kepivance<sup>®</sup> in Europe, North America, Australia and New Zealand and Stemgen<sup>®</sup> in three countries.
- Co-promotion or exclusive distribution agreements for four products in the Nordic market.

### Important events in 2009

#### Summary

- Operating profit before restructuring and other non-recurring costs amounted to SEK 16.2 M (40.2).
- Net revenues amounted to SEK 1,297.0 M (1,140.6) and the profit for the year before restructuring and other non-recurring costs was SEK 32.4 M (60.4), which represents earnings per share<sup>1</sup> of SEK 0.33 (0.66). The profit amounted to SEK 32.4 (-335.4) M, representing earnings per share<sup>1</sup> of SEK 0.33 (-3.67).
- Cash flow from operations was SEK 58.9 M (-506.5). Cash and cash equivalents and short-term investments as of December 31 amounted to SEK 306.6 M (460.1).

Implemented strategic initiatives:

- On November 5, 2009 Biovitrum announced the acquisition of Swedish Orphan. The transaction was concluded on January 14, 2010 and is being financed by a rights issue, an issue in kind and bank loans. The acquisition created a new specialist pharmaceutical company, Swedish Orphan Biovitrum, aimed at rare diseases. The mission of Swedish Orphan Biovitrum (SOBI) is to develop and make orphan drugs and specialist pharmaceuticals available to patients with rare diseases and significant unmet medical needs. SOBI has sales offices throughout Europe and representative offices in North America, extensive and comprehensive experience in business development and considerable product development and manufacturing capacity. The Group's product portfolio consists of some 60 orphan drugs and niche products. Several projects in late phases of development relating to rare diseases have significant potential for future value growth. Pro forma sales for 2009 for the new Swedish Orphan Biovitrum Group amounted to SEK 2 billion.
- AstraZeneca acquired all of the rights to Biovitrum's preclinical leptin modulator program aimed at treating obesity. The initial payment was EUR 6 M and Biovitrum will receive additional milestone payments linked to development phases and product sales, as well as a single digit percentage royalty on future sales.
- Cambridge Biotechnology Ltd (CBT) was sold to Proximagen Neuroscience plc.

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<sup>1</sup> Earnings per share have been adjusted for the bonus issue component of the new share issue which was concluded in January 2010.

- Biovitrum entered into a transfer agreement with iNovacia AB to further develop two projects for the treatment of metabolic diseases.
- Biovitrum signed an agreement with Karolinska Development AB to continue developing the leukemia project (FLT 3) within a jointly owned project company.
- In line with the new business strategy of focusing on protein drugs within specialist indications, the number of employees working with research and development was reduced. The last parts of the restructuring process were implemented in 2009, and following these measures, the number of employees in R&D was reduced from 353 at the end of 2007 to around 170 at the end of 2009.

Other events:

- Agreements were signed with Amgen to expand Biovitrum's Kineret<sup>®</sup> license to include certain new orphan indications.
- Biovitrum has signed an exclusive distribution and marketing agreement with Megapharm Ltd for the purpose of commercializing Kineret<sup>®</sup> and Kepivance<sup>®</sup> in Israel.
- Biovitrum and Affibody AB entered into a collaboration agreement which enables the development of new treatments that target inflammation and autoimmune diseases. The collaboration gives Biovitrum access to two unique patented technology platforms, Affibody<sup>®</sup> molecules and albumin binding technology, and thereby the ability to use these in its drug development.
- ReFacto AF<sup>®</sup> was approved for sale in Europe

The clinical portfolio developed well:

- In a phase I/IIa study the first patient has been given a dose of the long-acting rFVIII Fc, which is being developed in cooperation with Biogen Idec.
- Results from the first of two clinical phase II studies of Kiobrina<sup>™</sup> (rhBSSL) were positive. A statistically significant improvement in growth velocity in premature infants was observed and the safety profile was comparable to placebo.
- Biovitrum and Biogen Idec announced a decision to start a registrational trial of rFIX Fc for a longer-acting treatment of hemophilia B. After the end of the year, the first patients were recruited for an open-label registrational trial designed to analyze the effect, pharmacokinetics and safety of the long-acting protein rFIX Fc in hemophilia B patients (the B-LONG study). Biovitrum and Biogen Idec have constructed a partnership agreement for the companies' long-acting recombinant factor VIII Fc and factor IX Fc fusion protein for the treatment of hemophilia A and hemophilia B respectively. Under the agreement Biogen Idec will take primary responsibility for development and will cover the costs of the FIX Fc and FVIII Fc projects.
- An open-label explorative phase II study of Exinalda<sup>™</sup> (rhBSSL) in patients with cystic fibrosis and pancreatic insufficiency has been conducted. The primary objectives for the study were not reached. Biovitrum is now assessing options for continued development.
- Both the Multinational Association for Supportive Care in Cancer (MASCC) and the European Society for Medical Oncology (ESMO) recommend Aloxi<sup>®</sup> as the preferred 5-HT3 antagonist in preventing nausea and emesis in patients undergoing moderately emetogenic chemotherapy.
- A clinical phase II study of the safety and the therapeutic effect of Sym001 (immune thrombocytopenic purpura (ITP) and for Rhesus immunization prophylaxis) in ITP patients is progressing well at 23 clinics in Europe. Two dose cohorts have been treated and the independent safety committee has recommended proceeding to the next dose cohort.

## Sales and marketing

### Product Sales

Amounts in SEK million	2009	2008
Kineret®	440.7	25.8
Kepivance®	109.9	5.7
Aloxi®	9.4	5.3
Stemgen®	3.4	0.6
Novastan®	1.3	0.8
<b>Total</b>	<b>564.8</b>	<b>38.2</b>

The sales and marketing organization was expanded in 2009 with the addition of a number of key individuals. This improved competence and capacity with respect to the Kineret® and Kepivance® products. New marketing strategies are currently being developed in preparation to expand the markets for these products. The products were marketed actively for a couple of years before Biovitrum acquired them at the end of 2008. Biovitrum's work is beginning to have an impact; sales of Kineret® increased by 28 percent during 2009, calculated in local currency, in a comparison between the first and fourth quarters of 2009. During 2008 Kineret and Kepivance were included in revenues from product sales only in the second half of December.

Sales of Aloxi® in the Nordic region almost doubled in 2009.

### Co-promotion revenues

Amounts in SEK million	2009	2008
ReFacto®	89.7	80.2
BeneFIX®	11.2	10.4
Mimpara®	26.2	22.7
Kineret®	0.2	61.2
Kepivance®	0.0	0.2
<b>Total</b>	<b>127.3</b>	<b>174.7</b>

In 2009 Biovitrum launched ReFacto AF® in the Nordic Region. ReFacto AF® is an enhancement of ReFacto® (recombinant factor VIII for hemophilia A). ReFacto AF® is produced with the latest production technology without the use of human or animal components. The transition to ReFacto AF® was successful and new patients have also received this new therapy.

Co-promotion revenues from ReFacto® increased by 12 percent to SEK 89.7 M (80.2). Since Biovitrum took over sales of ReFacto® on July 1, 2004, the company has doubled product revenues by increasing the market share in the Nordic market.

BeneFIX® usage continued to increase and co-promotion revenues for BeneFIX® were up 8 percent on the previous year, SEK 11.2 M (10.4).

Co-promotion revenues for Mimpara® increased by 15 percent in 2009, SEK 26.2 (22.7).

Kineret® and Kepivance® are included in the product sales revenues as of 2009.

For production information, see [www.biovitrum.com](http://www.biovitrum.com).

## Manufacturing and contract development

Amounts in SEK million	2009	2008
ReFacto®	362.5	569.3
of which validation batches	—	47.0
Contract development	14.1	49.7
<b>Total</b>	<b>376.5</b>	<b>619.0</b>

Biovitrum is the sole global manufacturer of the active substance for ReFacto AF® (sold in the US under the name Xyntha®). The newly developed manufacturing process, entirely without the addition of human or animal components, has significant benefits compared to the previous process for ReFacto®. In addition to the exclusion of all foreign proteins, the new process also gives a higher yield, which enables production volume to be increased to meet a higher demand in the market in the future. To further increase the process capacity, a comprehensive modernization of the production facilities is under way. Manufacturing revenues for ReFacto® fell

by 36 percent in 2009 and amounted to SEK 362.5 M (569.3) for 2009. The volumes will continue to vary period to period as a result of Pfizer's production planning.

Other contract development revenues continued to decline to SEK 14.1 M (49.7) in 2009 as a result of the strategic decision to use the company's biopharmaceuticals competence to develop in-house projects and products.

### **Product development**

The purpose of Biovitrum's R&D project portfolio is to deliver new, attractive products within Biovitrum's focus area: protein drugs for specialist indications on a global market.

The portfolio currently consists of six phase II projects and one preclinical project. There are also several projects in the discovery phase.

Biovitrum has projects in the following indications: hemophilia/hematology, fat malabsorption and supportive cancer care.

The company's competence and resources in the areas of Clinical Development, Regulatory Affairs and Pharmacovigilance were increased in 2009, partly to manage the products acquired in 2008 and partly to handle late-phase development projects.

Biovitrum's R&D costs in 2009 amounted to SEK 569.4 M (670.6). The outlicensing and milestone revenues for the year amounted to SEK 62.6 M (132.5).

### **Development projects**

#### ***Factor IX Fc (rFIXFc) for the treatment of hemophilia B***

An open-label registrational trial that will be conducted at several clinical centers has recently begun. The study is designed to analyze the safety, pharmacokinetics and efficacy of Biovitrum's and Biogen Idec's long-acting recombinant factor IX Fc fusion protein (rFIXFc) in hemophilia B patients. The study, called the B-LONG study, will evaluate the efficacy of rFIXFc in the prevention and acute treatment of around 75 previously treated patients with severe hemophilia B.

#### ***Kiobrina™ for the treatment of fat malabsorption in premature infants***

The first clinical phase II trial in premature infants where rhBSSL is administered in infant formula is now concluded. The results are positive and show statistically significant improvement in the growth velocity. The safety profile was comparable to that of placebo and no drug-related, serious adverse events were reported. The second study, where rhBSSL is administered with pasteurized breast milk, is currently under way.

#### ***Sym001 for the treatment of immune thrombocytopenic purpura (ITP) and for Rhesus immunization prophylaxis***

A clinical study, demonstrating that Sym001 is capable of eliminating Rhesus D (RhD) positive red blood cells from the circulation of RhD negative healthy volunteers, has been finalized. A clinical phase II study with the aim of studying safety and efficacy of Sym001 in ITP patients is under way in Europe. Three out of four planned dose cohorts have been treated so far, and the independent safety committee has recommended proceeding to the last dose cohort.

#### ***Factor VIII Fc (rFVIII Fc) for the treatment of hemophilia A***

A phase I/IIa study of the long-acting fully-recombinant Factor VIII Fc fusion (rFVIII Fc) protein is under way. This open-label study will analyze the safety, tolerability and pharmacokinetics of rFVIII Fc in severe, previously-treated, hemophilia A patients. Biovitrum is working on this project with Biogen Idec

#### ***Kepivance® for the treatment of oral mucositis associated with blood cancer treatment in children***

A clinical study in children with acute leukemia undergoing stem cell transplants is currently under way. The primary purpose is to study safety and pharmacokinetics.

#### ***Exinalda™ for the treatment of fat malabsorption due to pancreatic insufficiency***

An open-label exploratory phase II study on Exinalda (rhBSSL) in patients with cystic fibrosis and pancreatic insufficiency has been completed. In terms of efficacy (coefficient of fat absorption), the primary end-point was not met. Biovitrum is currently evaluating the next steps for the continued development of Exinalda

## Operational risks

### Sales of ReFacto<sup>®</sup> and ReFacto AF<sup>®</sup>/Xyntha<sup>®</sup>

Sales of ReFacto<sup>®</sup> and ReFacto AF<sup>®</sup>/Xyntha<sup>®</sup> account for a significant proportion of Biovitrum's revenue. Under the company's agreement with Pfizer – which expires on December 31, 2015 – Biovitrum receives income both for contract development and manufacture of the pharmaceutical ingredients ReFacto<sup>®</sup> and ReFacto AF<sup>®</sup>/Xyntha<sup>®</sup> and for co-promotion from sales of ReFacto<sup>®</sup> and ReFacto AF<sup>®</sup>/Xyntha<sup>®</sup> in the Nordic region, as well as royalties from Pfizer's global sales of ReFacto<sup>®</sup> and ReFacto AF<sup>®</sup>/Xyntha<sup>®</sup>. In 2009 the combined revenues relating to ReFacto<sup>®</sup> amounted to around 48 percent of the company's total revenues, compared with 72 percent in 2008. Any material decrease in the revenues that the company receives from ReFacto<sup>®</sup> and ReFacto AF<sup>®</sup>/Xyntha<sup>®</sup>, whether due to reduced demand, increased competition, a deterioration in Biovitrum's capacity to develop the necessary quantities of pharmaceutical ingredient or to successfully market ReFacto<sup>®</sup> and ReFacto AF<sup>®</sup>/Xyntha<sup>®</sup>, changes in the company's agreement with Pfizer or for other reasons such as changed rules on government medicine subsidies for preventive treatments or a reduction in the spread of hemophilia, could have a material negative effect on Biovitrum's business, results and financial position. However, the company's dependence on ReFacto<sup>®</sup> and ReFacto AF<sup>®</sup>/Xyntha<sup>®</sup> has reduced as a result of the acquisition of the drugs Kepivance<sup>®</sup> and Stemgen<sup>®</sup> and the exclusive license for Kineret<sup>®</sup>.

The acquisition of Swedish Orphan will reduce the dependence on individual products.

### Sales of Kineret<sup>®</sup> and Kepivance<sup>®</sup>

Sales of Kineret<sup>®</sup> and Kepivance<sup>®</sup> account for a significant proportion of Biovitrum's revenue. In 2009 the combined revenues from Kineret<sup>®</sup> and Kepivance<sup>®</sup> amounted to SEK 550.6 M (31.5). Any material decrease in the revenues that the company receives from Kineret<sup>®</sup> and Kepivance<sup>®</sup>, whether due to reduced demand, increased competition, a deterioration in Biovitrum's capacity to provide the necessary quantities of pharmaceutical ingredient or to successfully market Kineret<sup>®</sup> and Kepivance<sup>®</sup> or for other reasons such as changed rules on state medicine subsidies or stock shortages, could have a material negative effect on Biovitrum's business, results and financial position.

The acquisition of Swedish Orphan will reduce the dependence on individual products.

### Increased globalization of operations

Biovitrum's acquisition in 2008 from Amgen of the drugs Kepivance<sup>®</sup> and Stemgen<sup>®</sup> as well as an exclusive license for Kineret<sup>®</sup> expanded Biovitrum's business considerably, and the company is now active on three continents. In 2008 the company built up an organization and structure for distribution and commercial operations in Europe, North America, Australia and New Zealand. International expansion is associated with uncertainty and makes great demands of organization and resources. The costs of establishing local distribution and sales channels are significant. Should it prove that the company does not have an adequate organization or sufficient resources for its increased globalization, or that the costs associated with the globalization exceed the company's estimates, this could have a material negative effect on Biovitrum's business, results and financial position. Increased globalization may also result in the company carrying on business in countries that typically have longer payment periods than its home market. Increased delays in payment could therefore also be a consequence of increased globalization and could have a material negative effect on Biovitrum's business, results and financial position. Moreover, increased globalization has made the company more dependent on contract partners for distribution, sales and manufacture. If such agreements are not renewed on similar terms or are terminated prematurely, this could have a material negative effect on Biovitrum's business, results and financial position.

### Future profit trend

Biovitrum receives significant revenues from Pfizer for ReFacto<sup>®</sup> and ReFacto AF<sup>®</sup>/Xyntha<sup>®</sup> and from sales of Kineret<sup>®</sup> and Kepivance<sup>®</sup> as well as from co-promotion or exclusive distribution agreements for the Nordic market. Although the company expects to continue to receive such revenues in the future, there are no guarantees that the revenues will be sufficient to make Biovitrum profitable in view of the company's research and development costs, and other costs. If these revenues ceases or decreases this could have a material negative effect on Biovitrum's business, results and financial position.

### Production facilities

Biovitrum is dependent on the production facility in Stockholm for the manufacture of ReFacto<sup>®</sup> and ReFacto AF<sup>®</sup>/Xyntha<sup>®</sup> being maintained and offering a high level of availability. If the facility or the equipment were seriously damaged, destroyed or if the facility had to be closed for some reason or if the company were unable to replace or repair damaged equipment quickly and cost-effectively, Biovitrum could lose revenue as a result of reduced production capacity, which could have a material negative effect on Biovitrum's business, results and

financial position. Although the company has insurance for damage to property and loss of production for an amount deemed sufficient by the company, it is not certain that the company could recoup these amounts in full or that amounts recouped would be sufficient to compensate for the losses suffered and lost revenue.

#### **Extensive quality requirements and controls**

Biovitrum manufactures recombinant protein pharmaceuticals. In addition, the company cooperates with pharmaceutical companies and companies in the biotech sector as regards the manufacture of pharmaceuticals developed by Biovitrum. The manufacture of recombinant protein pharmaceuticals requires precise and high quality manufacturing processes and controls, which means that the company must ensure that all manufacturing processes and methods and all equipment meet the requirements in force in respect of what is known as Good Manufacturing Practice (GMP requirements). Moreover, Biovitrum must perform extensive audits of its distributors, contract laboratories and suppliers that are covered by these requirements. GMP requirements control all aspects of the manufacture of pharmaceuticals, including quality control and quality assurance, manufacturing processes and procedures as well as documentation. The meeting of these standards demands that Biovitrum and its distributors, contract laboratories and suppliers achieve and maintain high quality manufacturing processes and controls that are sufficient to guarantee that the products meet current specifications and other requirements. Biovitrum's production facilities may be inspected at any time by the authorities and by the company's customers. Should such an inspection reveal deficiencies, Biovitrum could be forced to take measures, to stop production or to close the facility, which would disrupt manufacturing processes and have a negative impact on revenues. Should any of the company's cooperation partners fail to meet the standards/quality requirements in force, the company could not license in pharmaceutical projects or other products from that partner. Moreover, failure by Biovitrum or its subcontractors to achieve and maintain manufacturing standards that meet GMP requirements could result in manufacturing defects, which might lead to patients being injured or dying or in products being recalled, in delays or shortcomings in product tests or deliveries, high costs or other problems that could seriously damage the company's business.

#### **Manufacture of pharmaceutical ingredients**

Some of Biovitrum's candidate drugs in preclinical or clinical phases are based on recombinant technologies. The manufacture of proteins for use in pharmaceuticals in accordance with current regulations is complex, time-consuming and expensive. The company could face problems relating to inter alia production yield, quality control and guarantees, availability of qualified personnel, supply of raw materials, adequate training of existing personnel, the business not being run in accordance with the company's established routines or in accordance with the FDA's or other applicable regulations, production costs and the development of advanced production technology and process control. If the company would fail to operate its production facilities in an efficient manner, not obtain regulatory permits, not be able to produce sufficient volumes in time or in any other way run into any of the problems mentioned in the preceding paragraph, this could obstruct or lead to delays in the launch of the company's candidate drugs, which could have a material negative effect on Biovitrum's business, results and financial position.

### **Risks relating to research and development**

#### **Risks inherent in pharmaceutical development and the commercialization of products**

Developing a new drug up to and including its launch is both a capital-intensive and a risky process. The probability of getting to market increases as the project moves forward in the development chain, while the costs increase at a growing pace in the later clinical phases of development.

If Biovitrum cannot develop its existing or future project portfolio to later development phases, if developed candidate drugs cannot be manufactured at reasonable cost, if any of the development programs were to be delayed or if Biovitrum were unable to successfully commercialize any candidate drugs this could have a material negative effect on Biovitrum's business, results and financial position.

#### **Safety and efficacy criteria in conjunction with project development**

Before the launch of any of Biovitrum's candidate drugs is initiated the company and its cooperation partners must show that the candidate drug meets the stringent standards for safety and efficacy expected by the authorities in the countries in which Biovitrum plans to market the drug. Biovitrum has not yet received such authorization from the FDA, EMEA or any other authority for any of the candidate drugs in the product portfolio. The process of obtaining authorization generally requires extensive preclinical and clinical data, is very expensive and takes many years.

The FDA, EMEA and other authorities may delay, restrict or refuse authorization for a number of reasons, including that the candidate drug is perhaps not safe or effective, that the manufacturing processes or facilities that the company has chosen perhaps do not meet requirements in force or that changes in the authorities' authorization policies or the introduction of new rules may require additional work to be carried out. Even if the



company's candidate drugs meet the requirements of safety and efficacy in clinical trials, the authorities may take a different view to Biovitrum as regards the interpretation of data from preclinical studies and clinical trials and therefore refuse authorization. No guarantees can be given that Biovitrum will be granted marketing authorization for any of its existing or future candidate drugs. If Biovitrum does not succeed in obtaining marketing authorization for its existing or future candidate drugs, they will not be able to be marketed and sold. Authorities may also authorize a candidate drug for fewer indications than applied for or make the authorization conditional upon the performance of aftermarket studies. Delayed or limited permits, or failure to obtain permits, may prevent Biovitrum from achieving sufficient revenues from these candidate drugs and have a material negative effect on Biovitrum's business, results and financial position.

### **Clinical trials**

Biovitrum currently has six projects in clinical development and one project in preclinical development. Before the company can be authorized to launch any of its candidate drugs it must be shown that they are safe and effective through sufficient well-controlled preclinical studies and clinical trials. The number of preclinical studies and clinical trials that will be required varies depending on the candidate drug, indications, preclinical and clinical results and the rules that apply to the specific candidate drug. The company cannot predict with certainty when clinical trials in progress will be concluded, if they ever are, or when planned clinical trials will be initiated or concluded. Preclinical and clinical development is a long drawn-out and expensive process that is affected by many factors including those that are beyond the company's control, such as slower patient recruitment than expected and scheduling difficulties relating to staff and the clinical institutions that are to take part in the clinical trials. It is also difficult to predict exactly the costs associated with clinical trials, and the actual costs of implementing a clinical trial may exceed the budgeted costs. As a consequence, the results of and the total costs of Biovitrum's preclinical and clinical development projects are in themselves uncertain.

During clinical development it may emerge that the candidate drugs are not sufficiently effective or they may prove to have undesirable or unintended side effects, toxicities or other properties that may disrupt, delay or stop clinical development and prevent or limit the commercial application of the candidate drugs. Such results could lead to the company, its cooperation partners or the competent authorities for clinical trials suspending or cancelling clinical trials at any time.

Biovitrum cannot guarantee that any of the candidate drugs in the project portfolio will be developed into drugs that are safe and effective for use in humans or that these drugs will receive the necessary authorization for commercialization. Any deficiencies or delays in the implementation of clinical trials will reduce or delay Biovitrum's capacity to generate revenues from the commercialization of its candidate drugs and to maintain and supplement the project portfolio, which could have a material negative effect on Biovitrum's business, results and financial position.

### **Successes in early clinical trials are not necessarily indicative of the results in later clinical trial**

The results of Biovitrum's clinical trials in early stages are based on a limited number of patients and may be revised or nullified by authorities after further review or by clinical results at later stages. Historically speaking, the results of preclinical studies and early clinical trials in the industry have often not been indicative of the results obtained in later clinical trials. A number of new candidate drugs have shown promising results in clinical trials, but have later not succeeded in demonstrating the safety and efficacy required in order to obtain the necessary authorization. No guarantees can therefore be given that the information gathered from the preclinical studies and clinical trials of the company's candidate drugs will be sufficient to obtain authorization from the FDA, EMEA or any other authority.

Delayed or limited permits, or failure to obtain permits, could have a material negative effect on Biovitrum's business, results and financial position.

### **Commercial success and market acceptance for Biovitrum's products**

Even if the pharmaceuticals in Biovitrum's product portfolio were to receive authorization, it is not certain that any of these products would gain acceptance in the market among physicians, patients, procurement organizations and the medical world. The degree of market acceptance for each of Biovitrum's candidate drugs depends on a number of factors, including the following:

- the ability to produce acceptable proof of safety and efficacy,
- relative convenience and simple administration,
- the incidence and degree of any negative side effects,
- the availability of alternative treatments,
- price and cost effectiveness, and
- the effectiveness of Biovitrum's development partners' or licensees' sales and marketing strategy.

Biovitrum's success is further dependent on the products developed by the company being covered by and entitled to payment through private or state payment systems within the healthcare sector. Legislation and regulatory proposals in various European countries and in the US cover measures that could restrict or prevent payment for treatment with certain drugs. In certain cases such legislation has also resulted in the pricing of drugs being subject to state price controls. Payment for prescribed drugs varies significantly between different countries, with certain countries demanding that the products undergo time-consuming and demanding reviews in order to be able to be covered by the state payment systems. The use of drugs may also be affected by guidelines, recommendations and studies published by authorities and organizations.

If Biovitrum's drugs, despite being authorized, do not gain market acceptance or are not included in private insurance systems, state payment systems within the healthcare sector or become subject to legislation on medical treatment or pricing, or receive negative attention through guidelines, recommendations or studies published, this could have a material negative effect on Biovitrum's business, results and financial position.

#### **Cooperation with external parties**

Part of Biovitrum's strategy is to enter into various cooperation agreements, inter alia concerning joint development and licensing, with pharmaceutical and biotech companies for the development and launch of certain of Biovitrum's ingredients. The success of such partnerships will largely depend on the work of Biovitrum's partners or licensees, since these still have considerable right of determination over the work and resources that will be put into the projects. Biovitrum's cooperation partners or licensees may reprioritize matters internally, take a different view of the results of clinical trials, find themselves in a financial crisis or suffer staffing problems. Such factors may, individually or together, have a negative effect on their willingness or ability to develop Biovitrum's ingredients or to otherwise cooperate with Biovitrum. Moreover, many of the company's development partners and licensees are also competitors and it cannot be guaranteed that they will not have interests that conflict with Biovitrum's own interests. Neither can it be guaranteed that Biovitrum will succeed in the future in entering into cooperation and/or licensing agreements on terms acceptable to Biovitrum. Poor cooperation with partners and the inability to enter into or renew agreements could have a material negative effect on Biovitrum's business, results and financial position.

#### **Applications for authorization for licensed-in or acquired candidate drugs**

Many of the candidate drugs in Biovitrum's product portfolio are based on ingredients or technologies developed by other pharmaceutical or biotech companies that the company has licensed in or acquired by other means. Many of the preclinical studies and clinical trials carried out for these candidate drugs were carried out by companies before Biovitrum obtained a license or acquired the candidate drug. Problems with the studies/trials performed before such licensing or such acquisition could cause the company's applications to the authorities to be delayed or rejected, and even if the earlier studies/trials are acceptable to the authorities Biovitrum may need to devote more time and work to analyzing and presenting the results of the studies/trials. The costs of such work may be significant. Problems with earlier studies/trials may also require Biovitrum to redo some or all of these studies/trials, which could result in unforeseen costs or delays. Delayed or limited permits, or failure to obtain permits, could have a material negative effect on Biovitrum's business, results and financial position.

#### **Strengthening of the product portfolio**

An important component of Biovitrum's strategy is to develop a balanced product portfolio by, in addition to its internal research program, licensing in or otherwise acquiring the rights to potential new drugs. Licensing in and acquisitions of pharmaceutical products is a competitive enterprise and the company may not be able to obtain a license for or acquire further suitable candidate drugs or products from third parties. A number of more established companies also have a strategy of licensing in or acquiring products within the areas that the company focuses on. Such companies may have a competitive advantage over Biovitrum due to their size, financial position or greater capacity for clinical development and commercialization. If the company is unable to obtain rights for new drugs from third parties on terms acceptable to the company this could mean that Biovitrum is unable to create a balanced product portfolio, which could have a material negative effect on Biovitrum's business, results and financial position.

#### **Need for additional financing**

Biovitrum will need significant funds to carry on research and development of the company's potential products. Biovitrum may need to seek further external financing in the future and may do so inter alia through public or private financing. It may prove that further financing is not available at all or is not available on terms acceptable to Biovitrum.

Moreover, Biovitrum may need additional capital to finance future licensing in and acquisitions. It cannot be guaranteed that such financing will be obtainable in time or obtained on acceptable terms. If additional capital cannot be raised in time, Biovitrum may be forced to substantially limit its plans for in-licensing, acquisitions or

research and development, which could have a material negative effect on Biovitrum's business, results and financial position.

#### **Conflicts may arise between Biovitrum and its cooperation partners**

From time to time conflicts or differences of opinion arise between the company and its cooperation partners or counterparties regarding the interpretation of clinical data, the achievement of milestone payments, the interpretation of financial compensation for or the rights of ownership of patents and similar rights developed in cooperation. Any such conflict or difference of opinion may result in costs or delay, prevent or otherwise hinder the development and commercialization of Biovitrum's candidate drugs, which could have a material negative effect on Biovitrum's business, results and financial position.

### **Other business related risk**

#### **Competition**

The market for specialty pharmaceuticals is characterized by significant competition and rapid technology development. Biovitrum's competitors are, inter alia, international pharmaceutical, biotech and specialty pharmaceutical companies. Some competitors have significantly greater financial, technical and human resources. Biovitrum's competitors may have greater manufacturing, distribution, sales and marketing capabilities than the company. Moreover, there is always a risk that the company's product concepts are exposed to competition from similar products or to entirely new product concepts which prove to be superior. By allying itself with external research groups in the forefront of medical development, the company's chances to develop medical treatments that are competitive in the long-term increases. To further strengthen its own position, strong patent protection is a priority. The above described competition could have a material negative effect on Biovitrum's business, results and financial position.

#### **Parallel imports and pirated products**

It cannot be ruled out that differences in the price of drugs in the markets in which Biovitrum operates may result in increased parallel imports, whereby Biovitrum's products are purchased more cheaply on certain markets in order to then compete with Biovitrum's sales in other markets. Biovitrum thus cannot guarantee that the company's products will not be imported in parallel. Moreover, the supply of prescription drugs has come to face an increasing challenge from the fact that the distribution channels are vulnerable to illegal pirating and the supply of pirated products in an increased number of markets as well as on the Internet. With the increased demand for cheap pharmaceutical products, primarily in developing countries, pirated products have become an increasing problem. Biovitrum cannot guarantee that the company's products will not be at risk of attempted pirating, which could expose Biovitrum's patients to serious health risks. Pirated products do not meet the requirements of safety, but could be mistaken for the company's original products. Negative events caused by this could cause material financial losses due to damage to Biovitrum's reputation. Parallel imports and pirating could have a material negative effect on Biovitrum's business, results and financial position.

#### **Dependence on key personnel**

Biovitrum's success is dependent on key personnel in the company's executive management team. In view of these persons' knowledge within the pharmaceutical and biotech industry in general, and within the company in particular, the loss of one or more of these persons could have a material negative effect on Biovitrum's business, results and financial position.

The company's future development also depends in part on its continued ability to recruit and retain skilled personnel with the necessary expertise to run the business. If Biovitrum cannot continue to attract and retain such skilled personnel on terms acceptable to the company, Biovitrum could find it difficult to maintain or develop the business, which could have a material negative effect on the company's business results and financial position.

#### **Acquisitions**

In 2008 Biovitrum acquired the drugs Kepivance<sup>®</sup> and Stemgen<sup>®</sup> from Amgen and an agreement was concluded on an exclusive license for Kineret<sup>®</sup>. In the future the company may acquire further businesses or products that supplement or strengthen its current business or project portfolio. Future acquisitions of businesses or products could entail many operational and financial risks, which could have a material negative effect on the company's business, results and financial position, including the following:

- acquired drugs may not be successfully developed and successfully developed drugs may not achieve market acceptance,
- exposure to unknown commitments,
- higher costs than expected for acquisition and integration,
- difficulties and costs of integrating the operations and personnel of acquired companies with Biovitrum's operations and personnel,

- a deterioration in relations with key suppliers or customers of acquired companies due to changes in the corporate management and ownership,
- inability to retain key personnel of acquired companies, and
- significantly increased debt or increased dilution for existing shareholders as a result of payment in the company's own shares.

#### **Acquisition of Swedish Orphan**

The acquisition of Swedish Orphan was completed in January 2010. The operations of Swedish Orphan and Biovitrum are to a large extent exposed to corresponding risks. Apart from the risks that have been stated above, the following risk factors specific for Swedish Orphan are added. Each of them could have a material adverse effect on Swedish Orphan's, and the new group Swedish Orphan Biovitrum's, operations, performance and financial position.

The operational risks associated with Swedish Orphan are listed below:

- Sales of Orfadin<sup>®</sup> account for a significant proportion of Swedish Orphan's net sales. For 2009, this represented 40 percent Swedish Orphan's total net sales for the period.
- A majority of Swedish Orphan's net sales are obtained from contracted products and there is no guarantee that present agreements for these products can be maintained.
- Swedish Orphan relies on certain partners for a considerable part of its net sales. For example, Swedish Orphan is currently dependent on two partners: Shire Pharmaceuticals Ireland Ltd. for supply of the products Fosrenol<sup>®</sup>, Xagrid<sup>®</sup>, Mezavant<sup>®</sup> and Equasym<sup>®</sup>, and Ucyclid Inc for supply of the products Ammonaps<sup>®</sup> and Ammonul<sup>®</sup>.
- It cannot be guaranteed that Multiferon<sup>®</sup> will be a commercial success or will be authorized for its intended purpose in all Swedish Orphan's markets.  
Swedish Orphan recently launched Multiferon<sup>®</sup> in two Nordic countries. In 2010 the company intends to launch Multiferon<sup>®</sup> in 13 other European countries where the product has been authorized for two indications: (i) treatment of high-risk malignant melanoma and (ii) secondary treatment of patients who are intolerant to or do not respond to treatment with recombinant interferon, irrespective of the underlying disease. The market's acceptance of the product depends on, among other things, whether it can demonstrate clinical efficacy and safety, whether it is cost-effective, whether the administration is smooth and simple, and whether it has any advantages over alternative treatment methods.
- Patent protection for Orfadin<sup>®</sup> and Multiferon<sup>®</sup>  
Within Swedish Orphan there are 12 officially designated and/or approved orphan drugs. Orfadin<sup>®</sup> is patent protected up to and including 2017 and has market exclusivity as an orphan drug in Europe until February 2015, with a possible prolongation of two years through a pediatric investigation plan. Orfadin<sup>®</sup> is patent protected in the US up to and including 2013. Issued patents for the production process for Multiferon<sup>®</sup> within the EU and the US expires between 2010 and 2019.
- Tax risks and risks relating to social security contribution and other taxes in relation to Swedish Orphan's incentive program  
Swedish Orphan is subject to a number of taxes in Sweden. The tax authority could interpret the application of tax rules in a for Swedish Orphan unfavourable way. Particularly rules regarding social security contribution and other taxes in relation to incentive programs could be subject to different interpretations. Swedish Orphan has previously had incentive programs under which Swedish Orphan's employees were given the opportunity to acquire shares in Swedish Orphan. These incentive programs contained certain transfer restrictions for the acquired shares. The risk of the tax authority taking the position that all of the increase in the value of the shares, while they are subject to transfer restrictions, should be considered to be salary and not capital gains, cannot be ruled out.

The acquisition of Swedish Orphan poses risks:

- Integration of Biovitrum's and Swedish Orphan's operations.  
The transaction involves the integration of previously independent operations. Delays or difficulties that arise in connection with this integration could have a negative effect on Swedish Orphan Biovitrum's business after the transaction. One of the factors that the company has taken into consideration in connection with the transaction is the opportunities for synergy effects as a result of the transaction. There are no guarantees that

expected synergy effects, e.g. in the form of lower operating expenses and future costs or the utilization of Swedish Orphan's established infrastructure for sales and marketing in Europe, will be achieved or that additional integration costs will not be required in order to achieve synergy effects why it cannot be guaranteed that future financial targets are achieved. Failed, delayed or more costly integration of the two companies' businesses could have a material negative effect on Biovitrum's and Swedish Orphan Biovitrum's business, results and financial position.

- **Valuation of Swedish Orphan**  
The value of and consideration for Swedish Orphan were established using commonly used valuation methods and assumptions. The valuations may deviate from the businesses' future fair value and there is therefore no guarantee that the consideration paid by Biovitrum for Swedish Orphan will not exceed Swedish Orphan's future fair value.
- **Shareholders with significant influence**  
After the rights issue and the issue in kind that will be completed within the context of the transaction, Investor AB may subsequently – directly and indirectly – come to hold shares representing around 41 percent of the votes and capital in the Company. Moreover, assuming that it subscribes for its pro rata share in the rights issue, MPM Capital will hold shares representing around 13 percent of the votes and capital in the Company. Consequently, these shareholders, individually or together, will be capable of exerting a significant influence over all matters requiring approval by the shareholders. Investor AB and MPM Capital may also come to be able to prevent a change in controlling ownership and could take other actions that are beneficial to them, individually or together, but which disadvantage other shareholders.

#### **Product liability**

Although Biovitrum is not aware of any significant product liability claims against the company, the manufacture and sale of pharmaceutical products involves a significant risk of such claims. Although the company considers its product liability insurance to be adequate, no guarantees can be given that the insurance will cover future claims on the company. Moreover there could be a need to increase the insurance cover, which could lead to a material increase in costs or that a satisfying insurance cover could not be received. Product liability claims could result in significant costs for legal proceedings and damages, and a successful claim on the company beyond the available insurance cover, or a claim that results in significant negative publicity, could have a material negative effect on Biovitrum's business, results and financial position.

#### **Handling of environmentally harmful materials**

The company's research and development involves the controlled use of biological and hazardous materials and waste. The company is subject to laws and regulations controlling the use, manufacture, storage, handling and disposal of such materials. Although the company considers its safety routines for the handling and disposal of such materials to meet the prescribed standards, it cannot entirely eliminate the risk of accidental contamination or personal injury due to such material. Should an accident occur, Biovitrum could be held liable for damages or be punished by fines, and this liability could exceed the company's financial resources, which could have a material negative effect on the company's business, results and financial position. Moreover, Biovitrum may incur significant costs in order to comply with future environmental legislation and regulations.

#### **Exchange rate fluctuations**

The company's business is also subject to exchange rate risks. The majority of its expenses are incurred in SEK (Swedish kronor), while a significant proportion of its revenues accrue in other currencies. The international expansion brought about by the sale of Kepivance<sup>®</sup> and Kineret<sup>®</sup> means that the company's revenues will be generated in further currencies, while the royalty agreement for Wyeth's global sales of ReFacto<sup>®</sup> and ReFacto AF<sup>®</sup>/Xyntha<sup>®</sup> are based on sales mainly in US dollars and euro. As a result, a reduction in the exchange rate of US dollars, euro or other foreign currencies in which revenue is earned relative to SEK could have a material negative effect on Biovitrum's results and financial position.

Biovitrum has a part of its funding in USD. This also implies that the company's results and financial position is affected by the exchange rate fluctuation between USD and SEK.

To hedge future foreign exchange flows, the company has adopted the following policy on currency hedging.

- Based on forecasts, natural hedging (offset/netting of incoming and outgoing currency flows) should be applied as far as possible.
- Biovitrum will hedge the net foreign currency exposure as follows:

Currency flow	Expected maturity	Hedge ratio	Minimum amount
Known/Secure	< 1 year	80-100 %	SEK 1 million
Known/Secure	1-2 year	25-75 %	SEK 1 million
Known/Secure	2-3 year	0-50 %	SEK 1 million

### **Complex regulatory requirements for Biovitrum's business**

The regulatory requirements concerning the manufacture, testing and marketing of the company's candidate drugs and products are complex and may change over time. Changes to rules applicable to pharmaceuticals and biological products could increase Biovitrum's costs, limit opportunities for process development and manufacturing or hinder development of the company's candidate drugs and have negative effects on Biovitrum's ability to generate revenue.

### **The industry in which Biovitrum operates is to an increasing extent affected by price pressure**

The increased cost of medical treatment and healthcare in many countries leads to governments and other payers becoming more aware of the costs, which in turn leads to Biovitrum and the healthcare industry in general operating under strong price pressure. In most of the markets where Biovitrum is active, governments apply a certain control over the prices of drugs. The exercise of this control and its effects vary from country to country and different methods are applied on both supply and demand to control the costs of drugs. The introduction of new or extended measures for cost control of drugs could have a material negative effect on Biovitrum's business, results and financial position.

### **The company's IT system could suffer a crash, collapse or breach of security**

Biovitrum is dependent on a number of IT systems in its business. In order to be able to resume normal operations and alleviate any losses, the company has back-up processes and contingency plans for the recovery of lost data in the event of the collapse of an IT system. Nonetheless, the business could be disrupted, resulting in delays in manufacturing, product distribution, etc., which could have a material negative effect on Biovitrum's business, results and financial position.

### **Tax disputes and other tax risks**

Biovitrum is subject to different tax exposures due to a number of considerable restructurings and other transactions which the company has conducted or been part to, inter alia restructurings for the purpose of disposal of operations and real property. The company also has considerable sales in many countries outside Sweden, meaning that the company is exposed to complex regulations within the tax area, inside as well as outside Sweden.

The Tax Agency has, in April 2008 and October 2009 filed a request with the county administrative court in the county of Stockholm for the company to be taxed for an amount of SEK 234 M based on the application of the Swedish Tax Avoidance Act regarding a disposal of real property through a limited partnership (*kommanditbolag*). The company has disputed the claim. The case has not yet been decided by the county administrative court. Furthermore, on October 9, 2009 the Tax Agency submitted a new writ in which, based on two rulings by the Supreme Court on May 29, 2009, it presented new grounds for why the rules based on the Tax Avoidance Act regarding underpriced transfers should not be applied. Biovitrum believes that the Tax Agency should not win its case based on these new grounds either. The property, Paradiset 14, was transferred in 2004 to a company that was essentially a foreign-owned limited partnership company called Nya Paradiset KB and subsequently the shares in Nya Paradiset KB were sold to an external party at market price. The property was transferred to Nya Paradiset KB based on the rules regarding so-called underpriced transfers for a payment equivalent to the property's written-down value. The Tax Agency in a writ submitted to the county administrative court dated April 17, 2008 – based on the Tax Avoidance Act – has asked that the rules regarding underpriced transferred be disregarded. This means, according to the Tax Agency, that Biovitrum as a result of the transfer of the property to Nya Paradiset KB should be taxed for a capital gain of SEK 234.5 M. In Biovitrum's opinion it is entirely clear that the company has not acted in contrary to the purpose of the law in the manner claimed by the Tax Authority in the above-mentioned writ.

In case the company should lose these disputes, the company's losses carried forward can subsequently be reduced with considerable amounts. Levied tax penalties and VAT cannot be set-off against losses carried forward. The Group's losses carried forward from previous years amounts to a significant sum. Some of the losses carried forward are however blocked for utilization through group contributions during a certain number of years. Further, losses carried forward amounting to approximately SEK 76 M can have been, or may be definitely lost if a certain agreed additional purchase price does not fall out. Also in general, losses carried forward in the Group may, wholly or in part, be lost through changes in ownership.

### **Risks relating to intangible assets**

#### **Biotechnology, patent risks and intellectual property rights**

Biovitrum's success will largely depend on the company's or its licensor's ability to obtain protection in the US, EU and other countries for the intellectual property rights inherent in the products that the company develops, manufactures, markets and sells. The patent situation within the area of biotechnology and pharmaceuticals is

generally highly uncertain and involves complex legal and scientific issues. In these circumstances it is difficult for the patent authorities to correctly assess inventions that are the subject of patent applications in relation to prior art. It is not certain that either the company or its licensor will be able to obtain patents for its products or its technology. Even if a patent is granted, it may be contested, declared void or circumvented, which would both limit the company's ability to prevent competitors from marketing similar products and reduce the period during which the company enjoys patent protection for its products. Furthermore, it is not certain that the company's and its licensor's patent will provide adequate protection from competitors with similar products or technology. Since patent applications in the US and many foreign jurisdictions are not generally published until 18 months after they have been submitted, or in certain cases not at all, and since the publication of discoveries in the scientific literature often takes place long after the discoveries were actually made, neither the company nor its licensor can be certain that it was first to make the inventions in patents issued or in patent applications in progress, or whether it was the first to apply for protection of the inventions described in the patent applications.

There is thus no guarantee that products and processes that are covered by a patent granted will not come under attack or be contested by competitors or that patents granted do not infringe competitors' patents.

In the event for example that a third party has applied for a patent covering the same product or technology as Biovitrum's, the company could be forced to take part in proceedings to decide who holds the rights to the patent. The costs of such proceedings may be significant. Moreover, the company could lose such proceedings and thus the right to the patent. The inability to receive and retain a satisfying protection against intangible assets, which are included in the products that the company develop, manufacture, market and sell, could have a material effect on the company's business, result and financial position.

#### **Infringement of the intellectual property rights of others**

The technologies that the company uses in its research, or which are included in target products or candidate drugs that the company endeavors to develop and commercialize, may infringe patents or patent applications owned or controlled by others. A third party could take action against the company or its cooperation partners, which could force the company to pay significant damages. If an action in respect of patent infringement were to be brought against the company or its cooperation partners, it/they could be forced to cease or defer research, development, manufacturing or sales of the product or candidate drug that is the subject of the action. Consequently, the company or its cooperation partners could choose to seek, or be forced to seek, a license from the third party and thus in all likelihood be forced to pay license fees and royalties. It is not certain that these licenses will be available on acceptable terms or even available at all. Even if the company or its cooperation partners were able to obtain a license, the rights could be non-exclusive, which would provide the company's competitors with access to the same intellectual property rights. Finally, the company could be prevented from commercializing a product, or forced to cease some aspect of its business, due to claims relating to patent infringement, which could considerably damage the business.

Extensive legal disputes and other proceedings in respect of patents and other intellectual property rights have occurred in the pharmaceutical and biotech sector. In addition to a claim of infringement against the company, it could become party to other patent proceedings and other disputes, including what are known as interference proceedings as notified by the United States Patent and Trademark Office and recovery proceedings in the European Patent Agency in respect of intellectual property rights to the company's projects, products and technologies. Biovitrum is currently a party in two objection proceedings at the European Patent Agency concerning certain third party patents. No guarantees can be given that the results of such proceedings will be in Biovitrum's favor. Even if the ruling is in Biovitrum's favor, the costs incurred by Biovitrum could be significant. Certain of the company's competitors are better able to bear the costs of such legal proceedings and disputes than the company due to their significantly greater financial resources. Uncertainty as a result of the fact that patent legal proceedings and other proceedings have been instigated and are being continued could have a negative effect on Biovitrum's competitiveness. Patent legal proceedings and other proceedings could also take up a great deal of management time. For the above mentioned reasons, potential infringement of third party intellectual property could have a material negative effect on Biovitrum's business, results and financial position.

#### **Technology licenses**

Biovitrum is party to a number of technology licenses that are important for the business and the company is expected to be able to obtain further licenses in the future. The company has entered into license agreements with Amgen, Pfizer, Syntonix/Biogen Idec and a number of other cooperation partners. These licenses impose certain obligations on the company as regards commercialization, milestone payments, royalty income, insurance and other aspects. If the company fails to discharge these obligations, the licensor is entitled to terminate the license, as a result of which the company would be unable to market the products covered by the license concerned. Notice of termination by licenses could have a material negative effect on the company's business, result and financial position.

### **Trade secrets and know-how**

In addition to patented products and technologies, the company uses its own technology, own processes and own know-how that are not protected by patents. The company endeavors to protect such information, inter alia through confidentiality agreements with employees, consultants and cooperation partners. It is not certain that such agreements will provide protection from leaks of confidential information or that the agreements will provide sufficient compensation if breached. Moreover, the company's trade secrets may otherwise become known or may be developed independently by competitors.

If Biovitrum's own internal information and know-how cannot be protected for some reason, this could have a material negative effect on Biovitrum's business, results and financial position.

## **Employees**

### **Values and culture**

Biovitrum combines advanced research with commercial performance. Our operation has very high standards for our executives and other employees, and with respect to maintaining an innovative, high-performance corporate culture. Our values – commitment, new mind sets, accountability, and a focus on results – are all crucial to achieving our objectives. These values are expressed in our leadership and are reflected in processes such as employee performance evaluations. We use a specific method for management by objectives and follow-up called the performance management process. Supervisors and employees set annual individual goals together based on the general goals of the company. For employees to remain committed, they must understand the company's mission and objectives and how their own performance contributes to these. At the end of the year, efforts are evaluated and performances are rated.

### **Skills development and innovation**

Biovitrum is a knowledge-intensive company. Skills development is pivotal to improving our project portfolio so we can strengthen the production process and launch products. Employee skills development is linked to individual goals, which are based on operational and project needs. Many employees make a positive contribution to the operation through active participation in academic networks, with advantages such as access to new research findings.

### **Salaries and benefits**

Good employment terms are a prerequisite if Biovitrum is to recruit and retain qualified employees. Biovitrum therefore offers competitive salaries and benefits. The company applies the principle that salaries should be individual and differential, and they are determined by local salary criteria.

### **Working climate**

A good working climate leads to job satisfaction, low sickness absence and good relationships, and limits employee turnover. Therefore, we continuously conduct employee surveys to ensure a positive working climate. Managers and supervisors take the information from employee surveys very seriously and make changes in line with the survey results. We will continue to improve the flow of information from top management to the organization and further clarify what we expect from supervisors.

### **Diversity and equal opportunity**

The average number of employees in 2009 was 433 (485), with a good balance between men and women.

For Biovitrum, it stands to reason that everyone is offered the same opportunities and is treated equally, regardless of age, gender, religion, sexual orientation, disability or ethnic affiliation. We also strive to be a company where working life and private life can coexist within the framework of our operations.

### **Health and wellness**

Biovitrum aims for a work environment that promotes health and well-being, and sickness absences in 2009 was just below 2 percent. Employees are offered a favorable healthcare program through an agreement with Vitea, a company in the Feelgood Group, through which they are offered preventive health measures and a certain degree of medical care. In 2009, the company introduced a wellness portal where all employees can use an annual wellness allowance for different activities.



### **Work environment**

Biovitrum strives to fully comply with all work environment related laws and regulations, working systematically in this area, which is integrated with our environmental and quality assurance efforts. Our combined work environment and environmental policy emphasizes the significance of the work environment. The environmental policy is available on Biovitrum's website: [www.biovitrum.com](http://www.biovitrum.com). Formal work environment responsibility is delegated down the line. Each restricted area has an environmental group coordinator who helps the people in charge create a good work environment. They work with managers, safety representatives, and other employees to compile environmental action plans. Risk inventories and safety inspections focusing on ergonomics, chemicals, genetically modified microorganisms, electrical safety and radiation protection are performed regularly in restricted areas.

No workplace accidents were reported to the Swedish Work Environment Authority in 2009.

### **Respect for labor market regulations**

Biovitrum complies with and respects labor market regulations and agreements signed by parties in the labor market. We have a constructive partnership with trade unions and employer organizations and relations are good.

## **Remuneration for senior executives**

### **Board proposal for guidelines for remuneration to senior executives**

The board of directors proposes that the Annual General Meeting resolve to approve the board of directors' proposal regarding guidelines for remuneration for the management as set forth below which shall apply until the Annual General Meeting 2011. In this context, the management means the managing director of Biovitrum and the executives who, from time to time, are reporting to the managing director and who are also members of the senior management, as well as members of the board of directors to the extent consulting agreements are entered in to.

### **Motives**

Biovitrum shall offer a total remuneration in line with market conditions to enable the company to recruit and retain competent personnel. The remuneration to the management may consist of fixed salary, variable salary, pension and other customary benefits. Long-term incentive programs may be offered in addition to the above and will then be submitted to the Annual General Meeting for approval. The remuneration is mainly based on position, performance and the company's and the member's, respectively, performance in relation to objectives determined in advance.

### **Fixed salary**

The fixed salary for the managing director and the other members of the management shall be in line with market conditions and mirror the demands and responsibility that the position entails. The fixed salary for the managing director is reviewed once a year, as per January 1.

To the extent a member of the board of directors carries out work for the company or for another group company, in addition to the board work, consulting fees and other remuneration for such work may be payable.

### **Variable salary**

The variable salary for the managing director and the other members of the management shall be based on the company's fulfillment of objectives determined in advance. These objectives are determined for the promotion of the company's/the group's long-term development, value creation and financial growth and shall be designed in a way that does not encourage an excessive risk-taking. The variable salary may not amount to more than 50 per cent of the fixed salary for the managing director and not more than 30 – 50 per cent of the fixed salary for the other members of the management.

### **Long-term incentive programs**

Long-term incentive programs may constitute a complement to the fixed salary and the variable salary. The program participants are nominated based on competence, performance and to retain key employees with the company. The outcome is dependent on the fulfillment of certain predetermined performance requirements. The aim with having long-term incentive programs shall be to create a long-term commitment to Biovitrum, to offer the participants to take part in Biovitrum's long-term success and value creation and to create possibilities to attract and retain members of the management and key employees. For more information about Biovitrum's current incentive programs, see Biovitrum's annual report 2009, note 14.

### **Other remuneration and terms of employment**

The pension benefits for the managing director and the other members of the management shall preferably consist of premium based pension plans, but may also be defined-benefit pursuant to collective agreements.

The employment agreements with the members of the management may be terminated with a reciprocal notice period of up to six months. Upon termination by the company a severance payment is paid corresponding to maximum 18 monthly salaries. Upon a material change in the business, the employee is provided, under certain circumstances, with the possibility to terminate the employment with a right to severance payment in accordance with the above corresponding to maximum 12 monthly salaries. The managing director shall be entitled to severance payment corresponding to 18 monthly salaries in case of termination of employment due to a change of control of the company meaning that more than 50 per cent of the shares in the company are owned by one shareholder. However, the total severance payment for all members of the management may not exceed the existing salary for the remaining months up to the age of 65.

### **Deviation from the guidelines**

The board of directors may resolve to deviate from the guidelines if the board of directors, in an individual case, is of the opinion that there are special circumstances justifying that.

### **Share and option programs**

Biovitrum currently has three active option programs and two share programs. One of the three option programs was concluded in 2009. The programs are described in more detail in Note 14.

#### **Warrant program 2006/2008 for senior executives**

Prior to the initial public offering in 2006, Biovitrum repurchased warrants from the earlier option program (2001/2006) and certain senior executives instead subscribed for warrants in a new program. The purpose of this program was to continue to have an effective long-term incentive scheme for Biovitrum's senior executives. The number of warrants in this program was originally 2,326,136, with each warrant entitling the holder to subscribe for one share. In this program, the warrants were divided into four equal tranches with expiration dates of August 31, 2008, November 30, 2008, February 28, 2009, and May 31, 2009, and an issue price of SEK 59 per share. These warrants could be subscribed for beginning 12 months before the respective expiration dates.

In 2009 a total of 581,534 shares were issued in conjunction with warrant redemptions and 581,534 warrants expired in 2009.

This program was concluded in 2009 and there are no outstanding warrants.

#### **Employee option program 2006/2011**

In May 2006, 150,000 warrants were issued to be used in an option program for certain key individuals. Each warrant entitles the holder to subscribe for 3.78 shares<sup>2</sup>. The issue price per share based on these options is SEK 58.21<sup>2</sup> and the warrants expire on May 31, 2011. When allocated, the options entitle holders to earn an equal number of warrants, earning one-third of the total allocated warrants per year during the first three years. Options and their subsequent warrants are allocated free of charge (without payment).

In 2009, 5,000 options were surrendered and no options were issued. The number of outstanding options at year-end amounted to 35,000.

#### **Employee option program 2007/2012**

The 2007 Annual General Meeting resolved to initiate an employee option program for 2007/20012. As part of the plan, employee options may be issued with the right to acquire up to 567,000 shares<sup>2</sup> in the company. Each employee option may be exercised through April 1, 2012, to acquire 1.89 shares<sup>2</sup> in Biovitrum at an exercise price of SEK 58.21<sup>2</sup>. The right to acquire new shares under the employee option program will be exercisable with one-third of the total amount of employee options allocated from the date falling one year from the allocation date (the "anniversary date") and an additional one-third from each of the two subsequent anniversary dates, provided that the holder as of these dates is still employed by the company and has not been given notice of termination of employment.

All 300,000 employee options in this program have been allocated and at year-end the number outstanding was 300,000.

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<sup>2</sup> Adjusted for the new share issue completed in January 2010.

### **Share Program 2008**

The Annual General Meeting in 2008 resolved to approve a performance-based, long-term share program in 2008. Share Program 2008 is for Biovitrum's executives and key individuals and allows a maximum allocation of 433,952 shares<sup>3</sup> in Biovitrum AB (publ). The number of shares that may be acquired by program participants is based on the performance of the Biovitrum share calculated over a three-year performance period. The program was implemented in late 2008, and the performance period is from November 26, 2008 to November 25, 2011.

### **Share Program 2009**

The 2009 Annual General Meeting resolved to approve a performance-based, long-term 2009 share program. Share Program 2009 is for Biovitrum's executives and key individuals and allows a maximum allocation of 380,735 shares<sup>3</sup> in Biovitrum AB (publ). The number of shares that may be acquired by program participants is based on the performance of the Biovitrum share calculated over a three-year performance period. The program was implemented in 2009, and the performance period extends from June 10, 2009 to June 9, 2012.

### **Changes to the company's ownership structure**

The CEO and six of the senior executives have a clause in their employment agreements entitling them to certain rights in the event of a considerable change in the company, such as the company being transferred to a new dominating shareholder. The CEO will, in such a case, be entitled to terminate his employment with six months' notice and to receive severance pay equivalent to eighteen monthly salaries. The other six senior executives with such a clause in their agreement have the right to terminate their employment agreements and retain all benefits for twelve months without an obligation to work.

### **Environmental information**

Biovitrum's operation spans the entire value chain from research and development to marketing and sales. We strive to reduce our impact on the environment throughout the process. Environmental initiatives are a natural part of Biovitrum's operation and are integrated into our work environment and quality assurance efforts. The entire company follows an environmental management system that complies with the international standard ISO 14001. Our environmental policy emphasizes the significance of environmental issues. It is based on Biovitrum's business ethics and values and is the foundation for comprehensive, detailed environmental goals. The environmental policy is available on Biovitrum's website [www.biovitrum.com](http://www.biovitrum.com).

Biovitrum aspires to comply fully with all environmental laws and regulations. Formal responsibility for environmental issues is delegated down the line. Each restricted area has an environmental group coordinator who helps the people in charge create a sustainable process. They work with managers, safety officers, and other employees to compile environmental action plans. Risk inventories and safety inspections that include environmental issues are performed regularly in restricted areas.

Biovitrum's production facility is licensed for hazardous operations in compliance with the Swedish Environmental Code, with wastewater management conditions. Compliance with the terms of the permit is reported annually in an environmental report prepared for local licensing authorities. No violations of the terms were reported in 2009. In 2009, the production facility and other operations in adjoining premises consumed 128,254 m<sup>3</sup> of water and 13,203 MWh of energy, and generated 81.2 metric tons of waste, of which 69.9 metric tons was recyclable waste (including incineration with energy recovery), 8.6 metric tons of hazardous waste and 1 metric ton of refuse. Most of the hazardous waste is incinerated with energy recovery. Biovitrum is affiliated with REPA. The company has reportable operations in a few small facilities.

Biovitrum does not manufacture or import chemicals covered by the EU's REACH Regulation, but in 2009 we began preparing to adapt to the criteria that will be required of downstream users, and we communicate actively with our raw materials suppliers. Biovitrum has permits from the Swedish Work Environment Authority for handling specific chemicals and infectious agents, and contained use of genetically modified microorganisms, along with an import permit for animal byproducts from the Swedish Board of Agriculture.

Adaptation to current regulations has not yet affected Biovitrum's competitiveness or operations negatively, but we cannot predict the effects of future regulations.

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<sup>3</sup> Adjusted for new share issue completed in January 2010.

## Revenues and profit

### Four-year overview

Amounts in SEK million	2009	2008	2007	2006
Total revenues	1,297.0	1,140.6	1,256.4	1,201.1
Adjusted profit/loss for the period	32.4	60.4	79.0	92.7
Cost of goods and services sold	-375.7	-264.7	-348.8	-293.8
Research and development expenses	-569.4	-670.6	-694.3	-650.4
Operating profit/loss	16.2	-386.2	55.1	54.6
Financial items - net	16.3	20.2	23.9	39.6
Profit/loss for the period	32.4	-335.4	79.0	92.7
Earnings/loss per share <sup>1</sup> , SEK	0.33	-3.67	0.87	1.01
Earnings/loss per share after full dilution <sup>1</sup> , SEK	0.32	-3.67	0.85	0.93
Number of shares	50,396	49,815	45,623	45,623
Equity ratio	48.2%	49.8%	74.6%	66.5%

<sup>1</sup> Earnings per share have been adjusted for the bonus issue component of the new share issue, which was concluded in January 2010.

### Operating revenues

Operating revenues for 2009 amounted to SEK 1,297.0 M compared to SEK 1,140.6 M for 2008, with the following breakdown:

Amounts in SEK million	2009	2008
ReFacto <sup>®</sup> revenues	617.8	825.7
Revenues from other product sales	602.4	132.7
Other <sup>1</sup>	14.2	49.7
<b>Total revenues before licensing and milestone revenues</b>	<b>1,234.4</b>	<b>1,008.1</b>
Licensing and milestone revenues	62.6	132.5
<b>Total revenues</b>	<b>1,297.0</b>	<b>1,140.6</b>

<sup>1</sup> Other revenues includes e.g. research revenues, revenues from contract development and royalty from other products than ReFacto<sup>®</sup>

Licensing and milestone revenues in 2009 amounted to SEK 62.6 M (132.5).

Revenues from ReFacto<sup>®</sup> fell to SEK 617.8 M in 2009 compared to SEK 825.7 M in 2008. The total manufacturing revenues for the full year were SEK 362.5 M (569.3). This is due to a lower unit price for ReFacto AF<sup>®</sup>/Xyntha<sup>®</sup>. Royalty revenues for the sale of ReFacto<sup>®</sup> fell to SEK 165.6 M (176.2). Co-promotion revenues from sales of ReFacto<sup>®</sup> in the Nordic region increased by around 12 percent in 2009 to SEK 89.7 M (80.2).

Revenues from contract development and research agreements are recognized under "Other revenues." Revenues from contract development amounted to SEK 14.1 M (49.7). This is a result of the pronounced focus on the internal research projects at the expense of the external projects.

### Expenses

As a consequence of increased sales of Kineret<sup>®</sup> and Kepivance<sup>®</sup> the cost of goods and services sold was higher in 2009 than in 2008. The new product mix and lower licensing revenues had a negative effect on the gross margin, which was partially offset by an improved gross margin relating to the manufacture of ReFacto<sup>®</sup>. The gross margin excluding licensing and milestone revenues amounted to 69.6 percent (73.7). Also, ReFacto<sup>®</sup> production has led to better margins thanks to a high production yield and results, which also partly compensated for the effect of the gross margin as a result of the new product mix. In 2009 Biovitrum built up an inventory in preparation for the planned maintenance shutdown in the first half of 2010, and therefore production in 2009 was significantly higher than the demand in the market.

Research and development expenses were down 15 percent in 2009 compared to 2008, amounting to SEK 569.4 M (670.6). Biovitrum and Biogen Idec have constructed a partnership agreement for the companies' long-acting recombinant factor VIII Fc and factor IX Fc fusion protein for the treatment of hemophilia A and hemophilia B respectively. Under the agreement Biogen Idec will take primary responsibility for development and will cover the costs of the FIX and FVIII projects. The costs for the CBT entity amounted to SEK 32.3 M in 2009.

## **Profit**

The operating profit for 2009 amounted to SEK 16.2 M (-386.2). Excluding restructuring and non-recurring costs, the operating profit was SEK 16.2 M (40.2). The net financial income in 2009 was SEK 16.3 M (20.2).

The profit for 2009 amounted to SEK 32.4 M (-335.4).

## **Financial position**

Cash and cash equivalents and short-term investments as of December 31, 2009 amounted to SEK 306.6 M (460.1). Of this amount, SEK 129.6 M (193.7) were bank balances and SEK 128.6 M (60.5) investments in securities with a term of less than three months from the date of acquisition. These short-term investments are classified as cash and cash equivalents. Besides cash and cash equivalents, on December 31, 2009 the company had other short-term investments with a term of more than three months amounting to SEK 48.4 (205.9).

Cash flow from operations amounted to SEK 58.9 M (-506.5). Before payments relating to restructuring and building up the commercial structure, the cash flow amounted to SEK 132.3 M in 2008.

## **Investments**

The Group's investments in fixed assets in 2009 amounted to SEK 346.5 M (739.0), of which SEK 60.8 M relates to prepaid expenses related to acquisition in progress. Depreciation and write-downs amounted to SEK 109.7 M (267.5).

## **Taxes**

The company has accumulated a loss carry-forward, most of which has not been recognized as an asset. This means that the company's tax rate deviates from the Swedish tax rate. The company's tax expense amounted to SEK 0 M (30.6). In 2008 the company reversed a deferred tax liability of SEK 30.5 M.

## **Parent company**

The parent company reported revenues for the full year 2009 of SEK 1,297.0 M (1,140.6), operating profit of SEK 36.4 M (-244.5) and net profit of SEK 70.4 M (-393.0). Cash, cash equivalents and short-term investments as of December 31, 2009 amounted to SEK 306.4 M (on December 31, 2008, 458.1).

Shareholders' equity in Biovitrum AB (publ) as of December 31, 2009 amounted to SEK 1,326.1 M (December 31, 2008, 1,216.2).

## **Outlook**

Biovitrum has set a financial goal of increasing net sales for the new Swedish Orphan Biovitrum Group, which was formed when the acquisition was completed on January 14, 2010, from SEK 2 billion in 2009 to more than SEK 5 billion in 2015, with an operating margin (EBIT) exceeding 30 percent. This goal is based on the existing product and research portfolio, which means that sales and earnings generated by products that are acquired or licensed in the future will be an important part of the business.

## **Events after the balance sheet date**

- On 5 November 2009 Biovitrum announced the acquisition of Swedish Orphan. The transaction was concluded on January 14, 2010 and is being financed through a rights issue, an issue in kind and bank loans.
- Biovitrum and Biogen Idec have constructed a partnership agreement for the companies' long-acting recombinant factor VIII Fc and factor IX Fc fusion protein for the treatment of hemophilia A and hemophilia B respectively. Under the agreement Biogen Idec will take primary responsibility for development and will cover the costs of the FIX and FVIII projects.
- Biovitrum and Biogen Idec have recruited the first patients for an open-label registrational trial that will be conducted at several clinical centers. The trial has been designed to analyze the efficacy, pharmacokinetics and safety of the long-acting protein rFIXFc in hemophilia B patients (the B-LONG trial).

- A contract were signed with Amgen regarding an additional set of production of Kineret<sup>®</sup>-substance to meet an expected future increased market need of Kineret while Biovitrum is transferring the production process to a new supplier. In relation with this contract Biovitrum will resolve earlier agreed milestone remuneration for achieved sells levels of Kineret<sup>®</sup> and Kepivance<sup>®</sup>. The milestone remunerations amounts to a total nominal value of USD 60 M. Present value for these milestone remunerations are USD 51 M as per December 31, 2009.

## Changes in shareholders' equity

The consolidated shareholders' capital as of December 31, 2009 amounted to SEK 1,352.8 M, compared to SEK 1,285.0 M in December 2008.

During the year 813,119 shares were issued. 581,534 were issued when warrants were exercised and 213,585 in connection with the introduction of Share Program 2009.

## Shareholders

The total number of shareholders in Biovitrum at the end of 2009 was 5,562 (3,302). Biovitrum's largest shareholders were Investor AB with 22.9 percent of the capital and 23.1 percent of the votes and MPM BioVentures Funds with 12.4 percent of the capital and 12.5 percent of the votes. The 15 biggest shareholders together controlled 69.9 percent of the capital and 70.6 percent of the votes.

Share holder	Number of Shares	Share capital %	Share votes %
INVESTOR AB	11,647,307	22.9%	23.1%
MPM	6,305,104	12.4%	12.5%
ORKLA ASA	2,600,925	5.1%	5.2%
AMGEN INC	2,546,659	5.0%	5.0%
LIFE EQUITY SWEDEN KB	1,826,091	3.6%	3.6%
Catella Fondförvaltning	1,621,336	3.2%	3.2%
MERRILL LYNCH, PIERCE, FENNER & SMITH, W9	1,613,177	3.2%	3.2%
AAC CAPITAL	1,290,503	2.5%	2.6%
Skandia fonder	1,192,985	2.3%	2.4%
SVENSKT NÄRINGS LIV	1,100,000	2.2%	2.2%
Länsförsäkringar fondförvaltning AB	930,248	1.8%	1.8%
SEB PRIVATE BANK S.A., NQI	852,300	1.7%	1.7%
MSIL IPB CLIENT ACCOUNT	747,775	1.5%	1.5%
Carlson fonder AB	707,724	1.4%	1.4%
FJÄRDE AP-FONDEN	616,607	1.2%	1.2%
NORDEA BANK NORGE NOMINEE	603,220	1.2%	1.2%
GLADIATOR	490,000	1.0%	1.0%
SEB Investment Management	473,900	0.9%	0.9%
Handelsbanken fonder inkl XACT	417,039	0.8%	0.8%
FOLKETRYGDFONDET, JPMORGAN CHASE BANK	400,000	0.8%	0.8%
Biovitrum Treasury (C-shares, 1/10 vote per share)	515,585	1.0%	0.1%
Other	12,413,416	24.4%	24.6%
<b>Summa</b>	<b>50,911,901</b>	<b>100.0%</b>	<b>100.0%</b>

As a result of the issue in kind completed in January 2010 in connection with the acquisition of Swedish Orphan, Investor's shareholding increased to around 41 percent and MPM BioVentures Fund's shareholding was reduced to around 9 percent.

The total number of shares following the rights issue and issue in kind completed in January 2010, in connection with the acquisition of Swedish Orphan, amounts to 210,041,139.

## Share capital

Biovitrum's share capital at the end of the year was SEK 27,935,502 shared between 50,911,901 shares with a par value of SEK 0.55. The issued shares break down as 50,396,316 ordinary shares and 515,585 C shares. The ordinary shares carry one vote per share and the C shares 1/10 vote per share. All C shares are treasury shares.

In connection with Share Program 2008 the company issued 284,000 C shares and in connection with Share Program 2009 the company issued 231,585 C shares, a total of 515,585 C shares.

The share capital and number of shares changed in January 2010 as a result of the share issue completed in January 2010.

## The company's treasury shares

In 2009 Biovitrum acquired 231,585 treasury shares of share class C. The purchase price for the shares was SEK 127,372, which represents a share value of SEK 0.55. These shares represent 1.0 percent of the total number of shares in the company.

The long-term share program ("Share Program 2009") is the reason for the acquisition of the shares.

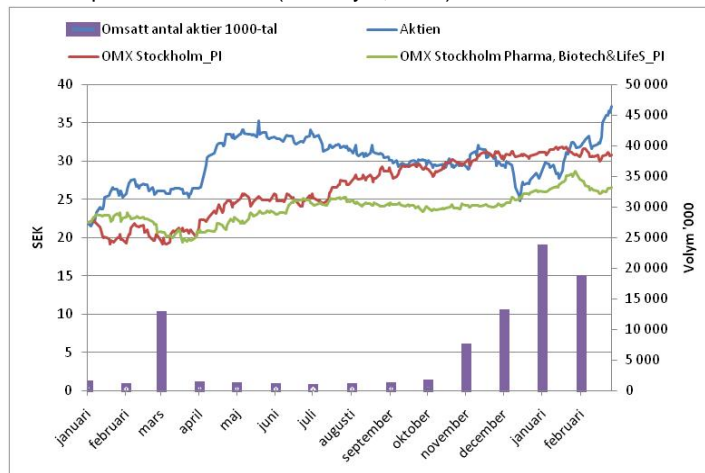
Below is a summary of the development within the company of the share capital and number of shares.

### Development of share capital and number of shares

		Change number of shares	Change share capital	Total share capital (SEK)	Total number of shares
Jan 2001	Founding of company	-	-	10,000,000	10,000,000
May 2001	Bonus issue	1,880,000	1,880,000	11,880,000	11,880,000
July 2001	Issue of shares	11,880,000	11,880,000	23,760,000	23,760,000
Apr 2006	Redemption of shares	-4,514,400	-4,514,400	19,245,600	19,245,600
Apr 2006	Bonus issue	2,405,700	4,514,400	23,760,000	21,651,300
Aug 2006	Split 2:1	21,651,300	-	23,760,000	43,302,600
Sep-Dec 2006	Issue of shares in connection with w warrant programs	2,320,100	1,273,032	25,033,032	45,622,700
Jun 2008	related to Arexis	142,422	78,147	25,111,179	45,765,122
Sep 2008	Issue of shares in connection with w warrant programs	250,502	137,450	25,248,628	46,015,624
Sep 2008	Issue of shares in connection with share based incentive program 2008	284,000	159,237	25,407,865	46,299,624
Nov 2008	Issue of shares in connection with w warrant programs	30,642	16,786	25,424,651	46,330,266
Dec 2008	Issue of shares in connection with purchase price related to Amgen products	3,768,516	2,064,393	27,489,044	50,098,782
May/Jun 2009	Issue of shares in connection with w warrant programs	581,534	319,086	27,808,130	50,680,316
Sep 2009	Issue of shares in connection with share based incentive program 2009	231,585	127,372	27,935,502	50,911,901
	Shares being held by Biovitrum				515,585

## The Biovitrum share

Biovitrum's share price<sup>1</sup> increased during the year by 26 percent, from SEK 22 per share at the beginning of the year to SEK 28 at year-end. The market capitalization was SEK 5.8 billion at the end of 2009. The Biovitrum share is on the OMX Nordic Exchange Stockholm's OMX Stockholm Pharma, Biotech&LifeS\_PI index, which rose during the same period by 18 percent. The highest price paid in 2009 was SEK 35 (May 19, 2009) and the lowest recorded price was SEK 21 (January 5, 2009).



<sup>1</sup> Adjusted for the bonus issue component of the new share issue which was concluded in January 2010.

## **Work of the Board**

The Board of Directors has nine members, including two employee representatives. The Board members possess considerable expertise in pharmaceutical research and science, developing and marketing pharmaceuticals, and in finance, accounting and strategic business development. Biovitrum's CEO has primary responsibility for presenting reports at Board meetings in 2009, but other company officials also participated in the Board's work as secretary or presenting reports. The Board works according to an agenda with recurring items to be dealt with at board meetings, such as the strategic situation, licensing, research, development and collaboration issues, acquisitions and investments, interim and annual accounts, and issues concerning the budget and audits. The Chairman leads and delegates assignments and ensures that important matters over and above the fixed items on the agenda are addressed. The Board's work is also regulated by rules of procedure established by the Board concerning the distribution of responsibilities between the Board members and the CEO.

The Board met 18 times in 2009 and throughout the year addressed issues relating to development of the R&D portfolio and suggestions for potential acquisitions and partnerships as well as Biovitrum's new strategy for the future.

The Board committees are preparatory bodies for the Board's decisions.

### **Audit Committee**

Biovitrum's Audit Committee has three members who are independent from corporate management: Mats-Olof Ljungkvist (chairman), Peter Sellei and Håkan Åström. CFO Göran Arvidson is the Committee's secretary, but is not a member of the Committee.

The Committee's primary task is to procure auditing services and handle matters concerning accounting, finances, financial reporting and auditing issues within the company. The Committee's responsibilities include an annual review of the independent auditors' proposals on the scope and methods of audits, preliminary examination of proposed changes to the accounting principles, and adjustments to accounting documents that affect financial reporting, consultation with management and the auditors regarding compliance with laws and regulations relating to financial matters, and an annual review of fees paid to the company's auditors.

During the year the committee met seven times. At these meetings the Committee discussed and followed up budgets and the outcome of budgets, all interim reports and financial schedules, as well as the evaluation process for Biovitrum's risk management and internal control.

The company's elected auditors also participated at two of the meetings during the year. These meetings addressed matters such as the auditors' planning of the audit, their observations and review of the company, remuneration to the auditors and the ongoing evaluation of risk management and internal control. For more information about remuneration to the company's auditors, please see Note 15 Fees and expenses paid to auditors. The company's cost for auditing assignments and advice for the 2009 financial year amounted to SEK 9,018 thousands (18,350) of which auditing fees amounted to SEK 3,629 thousands (2,295).

### **Compensation & Benefits Committee**

Biovitrum's Compensation & Benefits Committee consists of three members who are independent from corporate management. As of May 2009 the Committee consists of: Hans Glemstedt (chairman), Håkan Åström and Michael Steinmetz. The company's Head of Human Resources, Maria Berggren, is the Committee's secretary, but is not a member.

The role of the Compensation & Benefits Committee is to recommend guidelines and principles for the company's compensation programs. This responsibility includes oversight and proposals for remuneration to senior executives and proposals for incentive programs, pension plans and other issues relating to remuneration of the company's employees.

The Compensation & Benefits Committee met three times during the year. At these meetings the Committee discussed and followed up on annual pay scale revisions, bonuses for the CEO and senior executives and proposed guidelines, nominations and allotment of shares in Share Program 2009.

A specification of salaries and other remuneration for the CEO and senior executives can be found in Note 14 Employees, personnel costs and remuneration to the Board.



### Scientific Committee

Biovitrum's Scientific Committee has four members who are independent from management: Michael Steinmetz (chairman), Wenche Rolfsen, Peter Sellei and Hans Wigzell.

The Committee provides advice in scientific issues, evaluates the company's research strategies and follows up and reports to the Board of Directors on scientific trends and new research areas.

During the year the Committee met three times. At this meeting the main topics discussed were the development of research projects and the company's strategy focusing on specialist pharmaceuticals.

### Proposed appropriation of profit

The following funds are at the disposal of the Annual General Meeting:

Share premium reserve	SEK	464,749,676
Retained earnings	SEK	-37,265,019
Profit for the year	SEK	+ 70,429,433
Total	SEK	497,914,090

The Board of Directors and the Chief Executive Officer propose that the funds at their disposal, SEK 497,914,090, be carried forward.

## Consolidated statement of comprehensive income

SEK thousands	Note	2009	2008
	1-4		
Total revenues	6-7	1 296 973	1 140 583
Cost of goods and services sold	8	-375 740	-264 663
<b>Gross profit</b>		<b>921 233</b>	<b>875 920</b>
Sales and marketing expenses		-109 606	-51 775
Administration expenses		-193 295	-216 184
(of which expenses connected to product acquisition)		–	(-80 233)
Research and development expenses		-569 422	-670 559
Restructuring expenses		–	-346 163
Other operating revenue	10	43 262	34 298
Other operating expenses	11	-75 998	-11 732
<b>Operating profit/loss</b>	9, 12, 14-16, 19, 33	<b>16 174</b>	<b>-386 195</b>
Financial income	17	28 603	21 418
Financial expenses	18	-12 340	-1 220
<b>Financial items - net</b>		<b>16 263</b>	<b>20 198</b>
<b>Profit/loss before tax</b>		<b>32 437</b>	<b>-365 997</b>
Income tax expense	20	–	30 636
<b>Profit/loss for the year</b>		<b>32 437</b>	<b>-335 361</b>
<b>Other comprehensive income<sup>1</sup></b>			
Translation difference		-4 097	-23 636
<b>Comprehensive income for the year</b>		<b>28 340</b>	<b>-358 997</b>
Earnings/loss per share (SEK) <sup>2</sup>		0,33	-3,67
Earnings/loss per share after full dilution (SEK) <sup>2</sup>		0,32	-3,67
Number of shares (ordinary)		50 396 316	49 814 782
Average number of shares		50 142 990	45 973 714
Outstanding warrants		335 000	1 503 068
Number of shares after full dilution		50 766 316	51 357 850
Average number of shares after full dilution		50 793 547	48 368 497

<sup>1</sup> In correspondence with Revised IAS 1 all changes in equity that do not arise from transactions with owners should be reported in statement of comprehensive income. Translation differences does entirely concern equity in foreign subsidiary.

<sup>2</sup> For calculation, see disclosure "Changes in Equity"

Earnings per share have been adjusted for the bonus issue component of the new share issue which was concluded in January 2010.

## Consolidated balance sheet

SEK thousands	Note	2009-12-31	2008-12-31
<b>ASSETS</b>	1-4		
<b>Fixed assets</b>			
Intangible fixed assets	21	1,159,144	1,026,008
Tangible fixed assets	22	251,963	215,517
Financial fixed assets	24	102,707	34,426
Deferred income tax assets	26	11,800	11,800
<b>Total fixed assets</b>		<b>1,525,614</b>	<b>1,287,751</b>
<b>Current assets</b>	30		
Inventories	27	578,398	587,663
Accounts receivable, trade	28,32	105,203	75,035
Other receivables	28	33,109	33,660
Prepaid expenses and accrued income	29	256,567	134,645
Short-term investments	31,32	48,359	205,833
Liquid funds	31,32	258,280	254,228
<b>Total current assets</b>		<b>1,279,916</b>	<b>1,291,064</b>
<b>TOTAL ASSETS</b>		<b>2,805,530</b>	<b>2,578,815</b>
<b>SHAREHOLDERS' EQUITY AND LIABILITIES</b>			
<b>Shareholders' equity</b>			
Share capital		27,936	27,489
Other capital contribution		1,261,336	1,222,312
Other reserves		-27,733	-23,636
Retained Earnings		62,916	417,816
Net result		28,340	-358,997
<b>Shareholders' equity referring to the owners of the parent company</b>		<b>1,352,795</b>	<b>1,284,984</b>
<b>LIABILITIES</b>			
<b>Long-term liabilities</b>			
Deferred income tax liabilities	26	48,200	48,200
Other liabilities	34	290,348	397,113
Provisions for other liabilities and charges	35	365,645	377,905
<b>Total long-term liabilities</b>		<b>704,193</b>	<b>823,218</b>
<b>Short-term liabilities</b>			
Liabilities to credit institutions		50,000	–
Accounts payable		243,899	143,918
Current tax liabilities		568	21
Derivates	25	–	3,260
Other liabilities		136,770	12,520
Accrued expenses and prepaid revenues	36	310,221	211,568
Other provisions	35	7,084	99,326
<b>Total short-term liabilities</b>		<b>748,542</b>	<b>470,613</b>
<b>TOTAL SHAREHOLDERS' EQUITY AND LIABILITY</b>		<b>2,805,530</b>	<b>2,578,815</b>

## Consolidated changes in Shareholders' Equity

SEK thousands	Share capital	Other capital contribution	Other reserves	Profit/loss carried forward	Total share-holders' equity
<b>Shareholders' equity, Jan 1, 2008</b>	25 033	1 033 588	–	394 180	1 452 801
<b>Comprehensive income</b>					
Net profit/loss for the year				-335 361	-335 361
<b>Comprehensive income</b>				<b>-335 361</b>	<b>-335 361</b>
<b>Other comprehensive income</b>					
Translation differences			-23 636		-23 636
<b>Cash flow hedges:</b>					
Fair value, gains in year					68 681
Transfer to inventory and product rights					-68 681
<b>Other comprehensive income</b>	–	–	-23 636	–	-23 636
<b>Sum comprehensive income</b>	–	–	-23 636	-335 361	-358 997
<b>Transactions with shareholders'</b>					
Sharebased compensation		7 872			7 872
Redemption of shares		-155			-155
Issue of shares	2 456	181 007			183 463
<b>Sum transactions with shareholders'</b>	<b>2 456</b>	<b>188 724</b>	<b>–</b>	<b>–</b>	<b>191 180</b>
<b>Shareholders' equity, January 1 2009</b>	<b>27 489</b>	<b>1 222 312</b>	<b>-23 636</b>	<b>58 819</b>	<b>1 284 984</b>
<b>Comprehensive income</b>					
Net profit/loss for the year				32 437	32 437
<b>Comprehensive income</b>				<b>32 437</b>	<b>32 437</b>
<b>Other comprehensive income</b>					
Translation differences			-4 097		-4 097
<b>Other comprehensive income</b>	–	–	-4 097	–	-4 097
<b>Sum comprehensive income</b>	–	–	-4 097	32 437	28 340
<b>Transactions with shareholders'</b>					
Sharebased compensation		5 186			5 186
Redemption of shares		-153			-153
Issue of shares	447	33 991			34 438
<b>Sum transactions with shareholders'</b>	<b>447</b>	<b>39 024</b>	<b>–</b>	<b>–</b>	<b>39 471</b>
<b>Shareholders' equity, Dec 31 2009</b>	<b>27 936</b>	<b>1 261 336</b>	<b>-27 733</b>	<b>91 256</b>	<b>1 352 795</b>

Biovitrum's share capital at year-end was SEK 27,935,502 shared between 50,911,901 shares with a par value of around SEK 0.55. The issued shares break down as 50,396,316 ordinary shares and 515,585 C shares. The ordinary shares carry one vote per share and the C shares carry 1/10 vote per shares. All C shares are treasury shares. The share capital and number of shares changed in January 2010 as a result of the new issue concluded in January 2010.

In connection with Share Program 2008 the company issued 284,000 C shares and in connection with Share Program 2009 the company issued 231,585 C shares for a total of 515,585 C shares.

In 2009 Biovitrum acquired 231,585 class C treasury shares. The price paid for the shares was SEK 127,372, which represents a share value of SEK 0.55. The par value of the shares as of December 31, 2009 was SEK 0.55. The treasury shares represent 1.0 percent of the total number of shares in the company

The long-term share program (Share Program 2009) is the reason for the acquisition of shares.

## Earnings per share

Earnings per share before dilution is calculated by comparing the part of the profit assignable to the shareholders of the parent company divided by a weighted average of outstanding ordinary shares during the period, excluding redeemed shares.

To calculate the earnings per share after dilution, the average weighted number of outstanding shares is adjusted before the dilution effect of all potential ordinary shares.

	2009	2008		2009	2008
Net profit/loss referable to share-holders of the Parent company	32,437	-335,361	Net profit/loss referable to share-holders of the Parent company	32,437	-335,361
Average number outstanding ordinary shares (thousands)	50,143	45,974	Average number outstanding ordinary shares for calculation of earnings per share after dilution (thousands)	50,794	48,368
Earnings per share before dilution <sup>1</sup> (SEK per share)	0.33	-3.67	Earnings per share after dilution <sup>1</sup> (SEK per share)	0.32	-3.67

<sup>1</sup> Earnings per share have been adjusted for the bonus issue component of the new share issue completed in January 2010.

## Consolidated Cash Flow Statement

SEK thousands	2009	2008
<b>Operations</b>		
Profit/loss for the year	32,437	-335,361
Adjustment for items not affecting cash flow	16,408	190,647
<b>Cash flow from operations before change in working capital</b>	<b>48,845</b>	<b>-144,714</b>
<i>Change in working capital</i>		
Decrease(+) / Increase(-) in inventories	9,265	-503,070
Decrease(+) / Increase(-) in operating receivables	-147,028	-78,585
Increase(+) / Decrease (-) in operating liabilities	147,803	219,880
<b>Cash flow from operations</b>	<b>58,885</b>	<b>-506,489</b>
<b>Investment activities</b>		
Investment in operation <sup>1</sup>	-60,809	–
Divestment of operation	22,714	–
Investment in intangible fixed assets	-62,666	-180,733
Investment in tangible fixed assets	-96,049	-24,543
Divestment tangible fixed assets	2,104	8,110
Investment in financial fixed assets	–	-11,837
Divestment of financial fixed assets	-1,868	–
Investment/Sale of short term financial assets	157,474	188,733
<b>Cash flow from investment activities</b>	<b>-39,100</b>	<b>-20,270</b>
<b>Financing activities</b>		
Loans - Raising/Amortization	–	399,797
Issue of shares	34,438	16,588
Redemption of shares	-153	–
Repayment of bank loan	-50,000	–
<b>Cash flow from financing activities</b>	<b>-15,715</b>	<b>416,385</b>
<b>Net change in liquid funds</b>	<b>4,070</b>	<b>-110,374</b>
<b>Liquid funds at beginning of year</b>	<b>254,228</b>	<b>365,797</b>
<b>Exchange rate differences in liquid funds</b>	<b>-18</b>	<b>-1,195</b>
<b>Liquid funds at end of year <sup>2)</sup></b>	<b>258,280</b>	<b>254,228</b>

<sup>1</sup> Investment in operation relates to prepaid expenses acquisition in progress

<sup>2</sup> Not included in liquid funds is short term investments to a value of SEK 48.4 M (205.8) as per December 31, 2009.

## Supplementary disclosures to the consolidated Cash Flow Statement

SEK thousands	2009	2008
<b>Interest paid and received</b>		
Interest received	7 809	19 453
Interest paid	11 538	217
<b>Adjustments for items not affecting cash flow</b>		
Amortization/depreciation and write down of assets	109 664	267 507
Unrealised exchange rate differences	-6 765	–
Capital gain/loss from divestment of tangible fixed assets	-2 095	415
Capital gain/loss from divestment of financial fixed assets	21 540	–
Revaluation of present value of long-term liability	-12 260	–
Allocation of costs for options	5 144	–
Revaluation of financial fixed assets	4 663	-2 887
Pensions	-5 598	-5 166
Deferral of revenue from sale to Amgen	–	-132 466
Restructuring costs excl. write-downs	–	149 075
Payments relating to restructuring	-97 885	-63 153
Reversal of deferred tax	–	-30 550
Other items	–	7 872
	16 408	190 647
<b>Divestment of subsidiaries and other business units</b>		
<i>Divested assets and liabilities</i>		
Tangible fixed assets	1 942	–
Operating receivables	51 854	–
Liquid funds	398	–
<b>Total assets</b>	54 194	–
Operating liabilities	4 127	–
<b>Total liabilities</b>	4 127	–
Selling price	48 551	–
Deduction: Expenses in connection with divestment	-25 439	–
Selling price received	23 112	–
Deduction: Liquid funds in divested operation	-398	–
<b>Effect on liquid funds</b>	22 714	–
<b>Liquid funds</b>		
<i>Liquid funds include the following:</i>		
Cash and bank balances	129 594	193 621
Short-term investments equivalent to liquid funds	128 686	60 607
	258 280	254 228

The above items have been classified as liquid funds on the following basis:

- They are subject to minimal risk for fluctuation in value.
- They can immediately be converted into cash funds.
- They have a maximum maturity of three months from the initial date of validity.

## Income Statement – Parent Company

SEK thousands	Note	2009	2008
	1-4		
Total revenues	6-7	1,296,954	1,140,583
Cost of goods and services sold	8	-375,740	-264,665
<b>Gross profit</b>		<b>921,214</b>	<b>875,918</b>
Sales and marketing expenses		-109,605	-51,774
Administration expenses		-199,380	-221,162
<i>(of which expenses relating to product acquisition)</i>		–	(-80 233)
Research and development expenses		-570,689	-669,499
Restructuring expenses		–	-201,200
Other operating revenues	10	43,200	34,776
Other operating expenses	11	-48,338	-11,543
<b>Operating profit/loss</b>	9, 12, 14-16, 19, 33	<b>36,402</b>	<b>-244,484</b>
Result from participation in Group companies	13	17,625	-168,461
Financial income	17	28,705	21,111
Financial expenses	18	-12,303	-1,209
<b>Financial items - net</b>		<b>34,027</b>	<b>-148,559</b>
<b>Profit/loss before tax</b>		<b>70,429</b>	<b>-393,043</b>
Income tax expense	20	–	–
<b>Profit/loss for the year</b>		<b>70,429</b>	<b>-393,043</b>



## Balance Sheet – Parent Company

<i>SEK thousands</i>	<b>Note</b>	<b>2009-12-31</b>	<b>2008-12-31</b>
<b>ASSETS</b>	1-4		
<i>Fixed assets</i>			
Intangible fixed assets	21	959,672	826,536
Tangible fixed assets	22	251,963	211,673
Shares in Group companies	23	648,979	588,246
Financial fixed assets	24	21,359	19,489
<b>Total fixed assets</b>		<b>1,881,973</b>	<b>1,645,944</b>
<i>Current assets</i>	30		
Inventories	27	578,398	587,663
Accounts receivable	28	105,203	75,036
Current receivables	28	23,194	32,711
Receivables from Group companies		11,519	12,324
Prepaid expenses and accrued revenues	29	256,567	132,372
Short-term investments	31	48,359	205,833
Cash and bank balances	31	257,977	252,250
<b>Total current assets</b>		<b>1,281,217</b>	<b>1,298,189</b>
<b>TOTAL ASSETS</b>		<b>3,163,190</b>	<b>2,944,133</b>
<b>SHAREHOLDERS' EQUITY AND LIABILITIES</b>			
<i>Shareholders' equity</i>			
<i>Restricted equity</i>			
Share capital		27,936	27,489
Statutory reserve		800,257	800,257
<b>Total restricted equity</b>		<b>828,193</b>	<b>827,746</b>
<i>Non-restricted equity</i>			
Share premium reserve		464,750	425,614
Own shares		-308	-155
Profit/loss carried forward		-36,957	356,086
Net profit/loss for the year		70,429	-393,043
<b>Total unrestricted equity</b>		<b>497,914</b>	<b>388,502</b>
<b>Total shareholders' equity</b>		<b>1,326,107</b>	<b>1,216,248</b>
<b>LIABILITIES</b>			
<i>Long-term liabilities</i>			
Other liabilities	34	290,348	397,113
Provisions for other liabilities and charges	35	365,645	377,905
<b>Total long-term liabilities</b>		<b>655,993</b>	<b>775,018</b>
<i>Current liabilities</i>			
Liabilities to credit institutions		50,000	–
Accounts payable		243,899	141,317
Liabilities to Group companies		428,695	486,294
Derivates	25	–	3,260
Other liabilities		137,338	7,286
Accrued expenses and prepaid revenues	36	314,074	215,384
Other provisions	35	7,084	99,326
<b>Total current liabilities</b>		<b>1,181,090</b>	<b>952,867</b>
<b>TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES</b>		<b>3,163,190</b>	<b>2,944,133</b>

### Pledged Assets and Contingent Liabilities – Parent company

SEK thousands		2009-12-31	2008-12-31
Pledged assets	37	–	–
Contingent liabilities	37	78,444	40,654

### Changes in Shareholders' Equity – Parent Company

SEK thousands	RESTRICTED EQUITY		UNRESTRICTED EQUITY		Total share-holders' equity
	Share capital	Statutory reserve	Share premium reserve	Profit/loss carried forward	
<b>Shareholders' equity, Jan 1 2008</b>	<b>25,033</b>	<b>800,257</b>	<b>236,734</b>	<b>356,086</b>	<b>1,418,110</b>
Fair value, gains in year				68,681	68,681
Transfer to inventory and product rights				-68,681	-68,681
Issue of shares	2,456		181,008		183,464
Redemption of shares				-155	-155
Sharebased compensation			7,872		7,872
Net profit/loss for the year				-393,043	-393,043
<b>Shareholders' equity, Dec 31 2008</b>	<b>27,489</b>	<b>800,257</b>	<b>425,614</b>	<b>-37,112</b>	<b>1,216,248</b>
<b>Shareholders' equity, Jan 1 2009</b>	<b>27,489</b>	<b>800,257</b>	<b>425,614</b>	<b>-37,112</b>	<b>1,216,248</b>
Issue of shares	447		33,992		34,439
Redemption of shares				-153	-153
Sharebased compensation			5,144		5,144
Net profit/loss for the year				70,429	70,429
<b>Shareholders' equity, Dec 31 2009</b>	<b>27,936</b>	<b>800,257</b>	<b>464,750</b>	<b>33,164</b>	<b>1,326,107</b>

Biovitrum's share capital at year-end was SEK 27,935,502 shared between 50,911,901 shares with a par value of around SEK 0.55. The issued shares break down as 50,396,316 ordinary shares and 515,585 C shares. The ordinary shares carry one vote per share and the C shares carry 1/10 vote per shares. All C shares are treasury shares. Share capital and number of shares have changed in January 2010 in consequence of the share issue that was completed in January 2010.

## Cash Flow Statement – Parent Company

<i>SEK thousands</i>	<b>2009</b>	<b>2008</b>
<b>Operations</b>		
Loss for the year	70 429	-393 043
Adjustment for items not affecting cash flow	-24 631	249 319
<b>Cash flow from operations before change in working capital</b>	<b>45 798</b>	<b>-143 724</b>
<i>Change in working capital</i>		
Decrease(+) / Increase(-) in inventories	9 265	-503 070
Decrease(+) / Increase(-) in operating receivables	-144 883	-67 430
Increase (+) / Decrease (-) in operating liabilities	149 996	219 575
<b>Cash flow from operations</b>	<b>60 176</b>	<b>-494 649</b>
<b>Investment activities</b>		
Acquisition of subsidiaries <sup>1</sup>	-60 809	-25 015
Divestment of subsidiary	23 112	–
Investments in intangible fixed assets	-62 666	-165 718
Investments in tangible fixed assets	-96 081	-23 908
Divestment of tangible assets	2 104	8 110
Investment in financial fixed assets	-1 903	-11 837
Divestment of financial fixed assets	35	–
Divestment of short-term financial assets	157 474	188 734
<b>Cash flow from investment activities</b>	<b>-38 734</b>	<b>-29 634</b>
<b>Financing activities</b>		
Loan - Rasing	–	400 000
Issue of shares	34 437	16 588
Redemption of shares	-152	–
Amortization of loans	-50 000	–
<b>Cash flow from financing activities</b>	<b>-15 715</b>	<b>416 588</b>
<b>Net change in liquid funds</b>	<b>5 727</b>	<b>-107 695</b>
<b>Liquid funds at beginning of year</b>	<b>252 250</b>	<b>359 945</b>
<b>Liquid funds at end of year<sup>2</sup></b>	<b>257 977</b>	<b>252 250</b>

<sup>1</sup> Acquisition of subsidiaries relates to prepaid expenses in acquisition in progress

<sup>2</sup> Not included in liquid funds is short term investments to a value of SEK 48.4 M (205.8) as per December 31, 2009.

## Supplementary disclosures to Cash Flow Statement – Parent Company

SEK thousands	2009	2008
<b>Interest paid and received</b>		
Interest received	7 811	19 146
Interest paid	11 457	204
<b>Adjustments for items not affecting cash flow</b>		
Amortization/depreciation and write down of assets	107 574	119 304
Unrealised exchange rate differences	-6 765	–
Rvaluation of present value of long-term liabilities	-12 260	–
Capital gain/loss from divestment of fixed assets	-2 063	415
Capital gain/loss from divestment of financial fixed assets	-23 114	–
Revaluation of financial fixed assets	4 663	-2 887
Deferral of fees from Amgen	–	-132 466
Result from limited partnership	75	–
Write-down of shares in subsidiaries	–	168 460
Restructuring expenses excl. write-downs	–	149 076
Payments relating to restructuring	-97 885	-60 455
Other items	5 144	7 872
	-24 631	249 319
<b>Liquid funds</b>		
<i>Liquid funds include the following:</i>		
Cash and bank balances	129 291	191 642
Short-term investments equivalent to liquid funds	128 686	60 607
	257 977	252 250

The above items have been classified as liquid funds on the following basis:

- They are subject to minimal risk for fluctuation in value.
- They can immediately be converted into cash funds.
- They have a maximum maturity of three months from the initial date of validity.

## **Note 1 General information**

Biovitrum AB (publ), the parent company and its subsidiaries, collectively the Group, is a public, listed pharmaceutical company that markets specialist pharmaceuticals in a number of regions.

Biovitrum develops and sells specialist pharmaceuticals that improve people's lives. The company's business goal is to create a pharmaceutical company with long-term profitability through the international launch and sale of in-house developed and attractive products.

The company's expertise and capacity are focused on the development and production of biopharmaceuticals in our prioritized areas of hemophilia, inflammation/autoimmune diseases, supportive cancer care and fat malabsorption.

Revenues, including royalties and contract fees, finance most of the annual research budget.

The parent company is a limited company registered and headquartered in Stockholm, Sweden. The head office address is Tomtebodavägen 23A, Solna, Sweden.

The company has been listed as a mid-cap company on the Stockholm stock exchange (now NASDAQ OMX Stockholm) since September 15, 2006.

The consolidated financial statements for Biovitrum AB (publ) for the financial year ending on December 31, 2009 were approved by the Board of Directors and CEO on March 19, 2010 and will be submitted to the Annual General Meeting on April 27, 2010 for adoption.

## **Note 2 Significant accounting principles and basis for preparation of the parent company's and the consolidated financial statements**

### **Summary of significant accounting principles for group**

The primary accounting principles applied in the preparation of these consolidated financial statements are set out below. These principles have been consistently applied to all the years presented unless otherwise indicated.

The consolidated financial statements have been prepared in accordance with the Annual Accounts Act, the Swedish Financial Reporting Board's recommendation RFR 1.2. Supplementary Accounting Rules for Groups, and the International Financial Reporting Standards (IFRS) and IFRIC interpretations as adopted by the EU. The consolidated financial statements have been prepared according to the historical cost convention except in the case of financial assets and financial assets and liabilities (including derivative instruments) measured at fair value through profit and loss.

### ***Standards, amendments and interpretations that went into effect in 2009***

#### ***IFRS 7 (amendment) "Financial instruments – Disclosures"***

Effective as of January 1, 2009.

The amendment requires enhanced disclosures about fair value and liquidity risk, e.g. it requires a change in the disclosure of fair value at different levels in a fair value hierarchy. This amendment only requires additional disclosures and does not therefore affect the earnings per share.

Biovitrum is applying this amendment as of January 1, 2009.

#### ***IAS 1 (revised) "Presentation of Financial Statements"***

Effective as of January 1, 2009

The revised standard does not permit the presentation of income and expense items (i.e. changes in equity not relating to transactions with owners) in statements of changes in equity, and requires these changes to be presented in a comprehensive statement. The Group thus presents all owner-related changes in equity in the report "Changes in shareholders' equity, Group" and all changes not relating to transactions with shareholders in a statement called "Comprehensive statement."

Comparative information has been recalculated so that it is in line with the amended standard. This change to the accounting principle only affects the presentation of statements and has no impact on earnings per share.

Biovitrum is applying IAS 1 (amended) as of January 1, 2009.

#### ***IFRS 2 (amendment) "Share-Based Payment"***

Effective as of January 1, 2009.

The amended standard deals with vesting conditions and cancellations. It clarifies that vesting conditions are service conditions and performance conditions only. Other components in share-based payments are non-vesting conditions. These components need to be included in the grant date fair value for transactions with employees and others providing similar services. They do not impact the number of options expected to vest or valuation

thereof subsequent to the grant date. All cancellations, whether by the entity or by other parties, should receive the same accounting treatment. The Group is applying IFRS 2 (amendment) as of January 1, 2009. It has not had a material impact on the group's financial statements.

*IFRS 8 "Operating Segments"*

Effective from January 1, 2009

IFRS 8 Operating Segments replaces IAS 14 Segment Reporting. The new standard requires segment information to be presented from the management's perspective, which means presented on the same basis that is used for internal reporting. The basis for identifying reportable segments is the internal reporting as reported to and followed up by the highest decision-making executive. For Biovitrum, this is the Group's CEO.

Biovitrum is applying IFRS 8 as of January 1, 2009. Following the introduction of IFRS 8, the Group has not identified any new operating segments compared to those in the past. In connection with the acquisition of products from Amgen in December 2008, Biovitrum has sales in a number of geographical areas and from 2009 Biovitrum therefore reports revenues by geographical area.

***Standards, amendments and interpretations of present standards, not effective in 2009 and not applied prematurely by Biovitrum***

*IFRIC 17 "Distribution of Non-Cash Assets to Owners"*

Applies to the financial year commencing on July 1, 2009 or later.

This interpretation is part of the IASB's annual improvement project published in April 2009. The interpretation provides guidance on reporting agreements under which a company distributes non-cash assets to shareholders. An amendment has also been made to IFRS 5 where it is required that assets be classified as held for distribution only if they are assets for distribution in their current condition and distribution is very likely.

Biovitrum is applying IFRIC 17 as of January 1, 2010. This interpretation is not expected to have any material impact on the consolidated financial statements.

*IAS 27 (amendment) "Consolidated and Separate Financial Statements"*

Effective as of July 1, 2009.

The amended standard require the effects of all transaction with owners with a non-controlling interest (this term has replaced the previous one "minority interest") to be reported in equity if they do not involve any change in the controlling influence and these transactions no longer give rise to goodwill or gains and losses. The standard also states that when a parent company loses the controlling influence, any remaining portion should be reassessed at fair value and a gain or loss reported in profit and loss.

Biovitrum is applying IAS 27 (amendment) for future transactions with owners with a non-controlling influence as of January 1, 2010. IAS 27 (amendment) is not expected to have any significant effect on the consolidated financial statements.

*IFRS 3 (revised) "Business Combinations"*

Effective as of July 1, 2009.

The revised standard still requires the acquisition method to be applied for business combinations, but with some significant changes. For example, all payments for the purchase of a business at fair value are recorded on the acquisition date, while subsequent conditional payments are classified as liabilities which are then re-measured in profit or loss. Non-controlling interests (replacing the previous term "minority interest") in the acquired business can either be valued at fair value or at the proportionate portion of the business's net assets held by the party with the non-controlling interest. All acquisition related transaction costs are to be expensed. The revision applies prospectively for acquisitions after the date it goes into force. The amendment to the standard will not involve any change with respect to previous acquisitions, but will only affect reporting of future acquisitions. The Group is applying the standard from the beginning of the financial year commencing on January 1, 2010.

*IAS 38 (amendment) "Intangible Assets"*

The amendment is part of IASB's annual improvement project published in April 2009 and the Group will apply IAS 38 (amendment) from the date that IFRS 3 (revised) is applied.

The changes clarify procedures for fair value measurement of an intangible asset that was acquired through a business combination. According to the amendment, intangible assets are grouped together and treated as one asset if the assets have the same useful life.

The amendment will not have any material impact on the consolidated financial statements.

*IFRS 5 (amendment) "Non-Current Assets Held for Sale and Discontinued Operations"*

The amendment is part of IASB's annual improvement project published in April 2009.

The amendment explains that IFRS 5 specifies the disclosure requirements for non-current assets (or disposal groups) that have been classified as non-current assets held for sale or discontinued operations. It also explains that the general requirement in IAS 1 still applies, particularly IAS 1.15 (providing a fair presentation) and IAS 1.125 (sources of estimation uncertainty).

Biovitrum is applying IFRS 5 as of January 1, 2010. The amendment is not expected to have any material impact on the consolidated financial statements.

*IFRS 2 (amendment), "Group Cash-Settled and Share-Based Payment Transactions"*

The amendment incorporates IFRIC 8, "Scope of IFRS 2," and IFRIC 11, "IFRS 2 Group and Treasury Share Transactions" in the standard. The previous guidance in IFRIC 11 is also supplemented with information about classification of intra-group transactions not covered by the interpretation. The amendment is not expected to have a material impact on Biovitrum's financial statements.

**Consolidated accounts**

**General**

The consolidated accounts include the parent company and the subsidiaries.

**Subsidiaries**

Subsidiaries are all entities (including special purpose entities) over which Biovitrum has the power to govern the financial and operating strategies in a manner generally accompanying a shareholding of more than one half of the voting rights. Subsidiaries are included in the consolidated accounts from the date on which control is transferred to the Group. They are excluded from the consolidated accounts from the date that control ceases.

The acquisition method is used in the preparation of the consolidated accounts. The cost of an acquisition is measured as the fair value of the assets given, equity instruments issued and liabilities incurred or assumed on the transfer date, plus costs directly attributable to the acquisition. Identifiable assets acquired and liabilities and contingent liabilities assumed in a business combination are measured at their fair values at the acquisition date, irrespective of the extent of any minority interest. The excess of the cost of acquisition over the fair value of the Group's share of the acquired assets, and liabilities and contingent liabilities is assumed recorded as goodwill. Goodwill is not amortized according to plan but is instead tested annually for impairment. If the cost of acquisition is less than the fair value of the assets, and liabilities and contingent liabilities assumed of the subsidiary acquired, the difference is recognized directly in the income statement.

Intra-group transactions, balances and unrealized gains on transactions between Group companies are eliminated. Any unrealized losses are considered an impairment indicator of the asset transferred.

The accounting principles of the subsidiaries have been changed where necessary to ensure they are consistent with the principles adopted by the Group.

**Segment reporting**

Operating segments are presented from the management's perspective, which means presented on the same basis that is used for internal reporting. The basis for identifying reportable segments is the internal reporting as reported and followed up by the highest decision-making executive. For Biovitrum, this is the Group's CEO. Biovitrum is applying IFRS 8 as of January 1, 2009. Following the introduction of IFRS 8, the Group has not identified any new operating segments compared to those in the past. In connection with the acquisition of products from Amgen in December 2008, Biovitrum has sales in a number of geographical areas and from 2009, Biovitrum therefore reports revenues by geographical area. See Note 7.

**Foreign currency translation**

**Functional and reporting currency**

Items included in the financial reports for each of the Group's entities are measured using the currency of the primary economic environment in which the entity operates (the functional currency). The consolidated accounts are presented in Swedish kronor (SEK), which is the Parent Company's functional and reporting currency.

**Transactions and balances**

Foreign currency transactions are translated into the functional currency using the exchange rates that apply on the dates of the transactions. Exchange rate differences resulting from the settlement of such transactions and from the translation at year-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognized in the income statement.

**Translation of foreign subsidiaries**

The assets and liabilities of foreign subsidiaries are established in the respective functional currency, determined by the primary economic environment in which the company operates. For Biovitrum's foreign subsidiaries, all assets, provisions and other liabilities are translated at the exchange rate on the balance sheet date into the Group's reporting currency (SEK) and exchange rate differences arising from this are reported within other comprehensive income in the statement of comprehensive income. All items in the income statement are translated using the average exchange rate for the year.

Goodwill and fair value adjustments arising on the acquisition of a foreign entity are treated as assets and liabilities of the entity and translated at the exchange rate on the balance sheet date.

## **Revenues**

### ***Operating revenues***

Contract manufacturing revenues (ReFacto<sup>®</sup>) are reported when the goods have been delivered to the customer, i.e. when the responsibility for the risk associated with the goods has been transferred to the customer.

Revenue from the sale of pharmaceuticals is reported when the goods have been delivered from the company's consignment inventory to the end customer.

Revenue from service assignments is recognized when the economic outcome of the completed assignment can be reliably calculated and the economic benefits accrue to the Group.

The Group's revenues include revenue from licensing agreements, such as outlicensing revenue, milestone payments and royalties from third parties within the course of normal operations. According to the milestone method, successive milestones are considered as separate from initial licensing fees. The initial licensing fees are allocated over the duration of the licensing agreement since a separate earning period is not considered to have been completed when the fees are received. Subsequent milestone payments on the other hand are considered to belong to a separate completed part of the agreement. This portion of the revenue is recognized as soon as it is received, i.e. when the terms of the agreement have been met.

When the Group has undertaken to carry out research and development assignments and receives payment for services provided by the Group, this is recognized as deferred income and is recognized as and when work is carried out. Revenue from research collaboration is recognized in the period in which it is carried out. Milestone payments are recognized when they fall due for payment according to the agreement.

### ***Other operating revenues***

Other operating revenues are revenues from activities outside the normal operations. The item includes rental income and exchange rate gains on operating receivables and liabilities.

### ***Government grants***

Government grants are recognized when the company fulfills the requirements associated with the grant and when it can be established with certainty that the subsidy will be received. Grants received are recognized in the balance sheet as prepaid income and taken up as income in the period they are earned. Government grants are reported in the income statement as a reduction of the corresponding expense. Biovitrum receives government grants mainly in the form of research grants from the EU. A minor part of Biovitrum's projects are financed through government grants.

## **Classification etc.**

Within the Biovitrum Group, assets and liabilities are classified as either current or as long-term receivables and liabilities. Long-term receivables and liabilities consist essentially of the amounts for which payments are due more than one year from the balance sheet date. Current receivables and liabilities fall due within one year of the balance sheet date.

## **Intangible fixed assets**

### ***Goodwill***

Goodwill consists of the amount by which the cost of acquisition exceeds the fair value of the Group's share in the acquired subsidiary/associated company's net identifiable assets at the date of acquisition. Goodwill on acquisition of a subsidiary is included in intangible assets. In connection with the acquisition of associated companies, goodwill is included in the value of the holding in the associated company. Goodwill is tested annually for impairment and carried at cost less accumulated impairment write-downs. Gains and losses on the disposal of an entity include the carrying amount of goodwill relating to the entity sold. If the net fair value of the acquired operation's identifiable assets, liabilities and contingent liabilities exceeds the acquisition cost, the surplus (negative goodwill) is immediately reported in the income statement.

### ***Licenses and patents***

Licenses and patents are reported at cost. Licenses and patents have a finite useful life and are carried at cost less accumulated amortization. Amortization is calculated using the straight-line method to allocate the cost of licenses and patents over their estimated useful lives.

### ***Research and development costs***

Expenditure for a development project is recognized as an intangible asset if the company can prove that it is technically possible to complete and profitably commercialize the results and only if the expenditure for the project can be measured in a reliable way. Amortization is calculated using the straight-line method to allocate the cost of development projects over their estimated useful lives, and is implemented once the development project starts to



generate revenues. Other development expenditure is recognized as incurred. Biovitrum's research involves the discovery stage of research and all research expenditure is subsequently expensed.

**Acquired R&D**

Expenditures for acquired research and development projects are recognized as intangible assets. When an acquired research project begins to generate revenue, amortization begins and continues over the project's estimated useful life. Research and development projects are tested at least a once a year for impairment.

**Software and IT projects in progress**

Acquired software licenses are capitalized on the basis of the costs incurred when the software in question is acquired and put into operation. These costs are amortized over the estimated useful life of the software.

Costs associated with developing or maintaining software are recognized as an expense as incurred. Costs directly associated with identifiable software products developed specially for Biovitrum, which are controlled by the Group and are likely to generate economic benefits exceeding costs beyond one year, are recognized as intangible fixed assets. Direct costs include the software development employee costs and a reasonable portion of relevant overhead.

Expenditure to enhance the performance of software or extend its useful life (development costs) beyond the original plan is capitalized and added to the initial cost of the software.

Amortization according to plan for computer programs that have been recognized as fixed assets is done using the straight-line method over the program's useful life up to a maximum of three years.

**Tangible fixed assets**

Tangible fixed assets are recognized as assets in the balance sheet if it is likely that future economic benefits will accrue to the company and the cost of the asset at acquisition can be calculated in a reliable way.

All tangible assets are stated at cost less depreciation. Cost includes expenditure that can be directly attributed to the acquisition of the asset. Additional expenditure increases the carrying amount of the asset or is reported as a separate asset, depending on which is appropriate, only when it is probable that future economic benefits associated with the asset will accrue to the Group and the initial cost of the asset can be measured in a reliable way. All other forms of repair and maintenance are reported as expenses in the income statement in the period in which they are incurred.

**Depreciation of tangible fixed assets**

Depreciation according to plan of tangible fixed assets is based on the asset's useful life. Depreciation is calculated on a straight-line basis over the asset's estimated useful life. The following depreciation plan applies:

Machinery and technical equipment

Laboratory equipment and other investments	3-7 years
Other major investments	10 years

Equipment, tools, fixtures and fittings

Computers	3 years
Servers and other major computer hardware items	3-5 years
Furniture, fixtures and fittings	5-10 years

The residual value and useful life of the assets are assessed at each closing day and adjusted as needed.

An asset's carrying amount is written down to its recoverable amount if the asset's carrying amount exceeds the estimated recoverable amount.

Gains or losses from the sale or disposal of tangible fixed assets are determined by comparing the difference between the sale price and the carrying amount less direct selling expenses. The profit/loss item is reported as other operating revenues and other operating expenses respectively.

**Leased assets**

Leases are classified in the consolidated accounts either as finance or operating leases. Leased fixed assets where Biovitrum is responsible for the same risks and benefits as in the case of direct ownership are classified as finance leases. Accordingly, the asset is reported as a fixed asset in the balance sheet. Corresponding commitments of future lease charges are reported as current or long-term liabilities. The leased assets are depreciated according to plan, while lease payments are reported as interest and repayment of debt. Leased

assets where the lessor essentially retains ownership of the assets are classified as operating leases and lease charges are expensed on a straight-line basis over the term of the lease.

***Write-downs of non-financial assets***

Assets with an indeterminable useful life and intangible assets not yet taken into operation, are not depreciated but are instead tested annually for impairment. Assets that are written down are assessed to determine if the value has decreased where events or changes in circumstances indicate that the carrying amount may not be recoverable. The write-down is the difference between the carrying amount and the recoverable amount where the recoverable amount is defined as the greater of the asset's net realizable value and its value in use. When testing for impairment, assets are grouped at the lowest levels at which there are separate identifiable cash flows (cash-generating units). Since Biovitrum has made the assessment that the Group's operations comprise a business segment, the Group as a whole is considered to be the smallest cash-generating unit. A write-down is reversed if there has been a change in the conditions that were the basis for determining the recoverable amount. Reversal amounts do not exceed the carrying amount that would have been recognized, less depreciation, if no write down had been performed. Impairment losses on goodwill are not reversed. Impairment testing of goodwill and capitalized research and development projects are described in Note 21.

According to IAS 36, an asset is impaired if its carrying amount exceeds its recoverable amount, where the recoverable amount is defined as the higher of the asset's net realizable value and its value in use. When calculating value in use, the future cash flow that the asset is expected to generate is deducted using an interest rate that corresponds to Biovitrum's weighted cost of capital.

**Financial assets**

The Group classifies its financial instruments in the following categories: loan receivables and accounts receivable, financial assets measured at fair value through profit or loss, held-to-maturity investments and available-for-sale financial assets. Classification depends on the purpose for which the instrument was acquired. Management determines how the instruments will be classified in connection with initial recognition and reviews this decision on each reporting occasion. At present, Biovitrum has financial assets measured at fair value through profit or loss and accounts receivable.

***Loans and accounts receivable***

Loans and receivables are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. They are included in current assets, except for maturities greater than twelve months after the balance sheet date which are classified as fixed assets. The Group's loans and accounts receivable are classified as accounts and other receivables as well as cash and cash equivalents in the balance sheet.

Bank balances, loan receivables and accounts receivable are measured at cost.

***Financial assets measured at fair value through profit or loss***

Financial assets measured at fair value through profit or loss are financial assets held for trading. A financial asset is classified in this category if acquired principally for the purpose of selling in the short term. Assets in this category are classified as current assets.

***Available for sale financial assets***

Available-for-sale financial assets are non-derivatives that have been identified as available for sale or not classified in any of the other categories. They are included in the fixed assets unless management intends to dispose of the investment within twelve months of the balance sheet date.

Purchases and sales of financial assets are recognized on the trading date, i.e. the date on which the Group commits to purchase or sell the asset. Financial instruments are initially recognized at fair value plus transaction costs for all financial assets not carried at fair value through profit or loss. Financial assets carried at fair value through profit or loss are initially recognized at fair value and transaction costs are expensed in the income statement.

Financial assets reported in the balance sheet include, on the assets side, cash and cash equivalents and accounts receivable. Liabilities and shareholders' equity include accounts payable, issued debt and equity instruments and borrowing. Currency derivatives are stated either as assets or liabilities, depending on the fluctuation in exchange rates. Currency derivatives are mainly formed through forward contracts in USD.

A financial asset or liability is entered in the balance sheet when the company becomes party to the instrument's contractual terms and conditions. Accounts receivable are entered in the balance sheet when the invoice is dispatched. Liabilities are entered when a contractual obligation exists for the counterparty to pay, even if the invoice has not yet been received. Accounts payable are entered when the invoice is received.

A financial asset is derecognized from the balance sheet when the rights under the agreement have been exercised, have expired or the company has lost control over them. The same applies for parts of a financial asset. A financial liability is derecognized from the balance sheet when the contractual obligations have been fulfilled or otherwise expired. The same applies for parts of a financial liability.

Gains or losses arising from changes in the fair value of the financial assets measured at fair value through profit or loss are presented in the income statement in the period in which they arise within other losses/gains net or current investments under financial income.

The fair value of listed securities is based on current quoted market prices. The Group has a number of short-term investments with a term of more than three months. If a market for a financial instrument is not active, the Group establishes the fair value applying measurement techniques such as using information about recent arm's length transactions, reference to the fair value of another instrument that is essentially the same, company acquisition agreements and discounted cash flow analysis and option pricing models. The same principle applies for unlisted securities. Also, market information is used to the greatest extent possible. Company-specific information is used to the least extent possible. The Group has investments in unlisted securities.

On each reporting occasion, the company evaluates whether there is objective proof of impairment of a financial asset. A gain or loss on a financial asset or liability measured at fair value through profit or loss is recognized in the income statement. A gain or loss on a financial asset in the category of available-for-sale financial assets is reported directly in equity, under changes in shareholders' equity.

#### **Derivative instruments**

Derivative instruments consist of currency forward contracts that are used to hedge the risk of exchange rate fluctuation. All derivatives are assigned a market value and the market values are reported in the balance sheet. The accounting method for the profit or loss which occurs in connection with a revaluation depends on if the derivative is identified as a hedge instrument and if so, on the character of the hedged item.

Biovitrum's transaction exposure in foreign currencies arises due to the company's exports and imports of goods paid for in foreign currencies. Currency exposure relating to forecast future flows is hedged as necessary primarily through currency forward contracts. The forward contracts are recognized in the balance sheet at fair value. Changes in value are reported directly in the income statement. The hedged flows may be both contracted and forecast transactions.

#### **Borrowing**

Borrowing transactions are initially reported at fair value, net after transaction costs. Borrowing is thereafter reported at amortized costs and any difference between the received amount and repaid amount is reported in the income statement distributed over the loan period, applying the effective rate method.

Borrowing is classified as short-term liabilities, unless the Group has an unconditional right to defer the liability no less than 12 months after balance day.

#### **Inventories**

Inventories are valued at the lower of cost and net realizable value. Cost is calculated using the first in, first out principle (FIFO). The net realizable value is the expected sales price in continuing operations less selling expenses. Obsolescence risk and established obsolescence have been taken into account.

#### **Accounts receivable**

Accounts receivable are measured at amortized cost and reported at the amounts that are expected to be received after deductions for possible doubtful receivables after individual assessment. The terms for accounts receivable are short and their value is therefore initially recognized at nominal amounts without discounts. Write-downs of accounts receivable are reported as operating expenses.

#### **Cash and cash equivalents**

The parent company's and the Group's cash and cash equivalents include the balances on the Group's common accounts and other bank accounts, as well as investments with a term of less than three months from the date of acquisition. This means that the Group's cash and cash equivalents are only exposed to minimal risk of value fluctuations.

### **Shareholders' equity**

Ordinary shares are classified as equity. Transaction costs directly attributable to the issue of new shares or options are reported in equity, net after tax, as a deduction from the proceeds. When a Group company purchases shares in the parent company (treasury share buy-back), the purchase price paid including any costs directly related to the transaction (net after tax) reduces the profit carried forward until the shares are withdrawn or sold. If these shares are subsequently sold, the payment received (net after any direct transaction costs and tax effects) are reported in the profit carried forward.

### **Provisions**

Provisions are recognized in the balance sheet when Biovitrum has a legal or constructive obligation as a result of an event that has occurred and where it is probable that an outflow of resources will be required to fulfill the obligation. It must also be possible to make a reliable estimate of the amount. Provisions are recognized in the amount corresponding to the best estimate of the payment required to fulfill the obligation. If the outflow of resources is expected to take place at a point far in the future, the expected future cash flow is discounted and the provision is recognized at its present value. Provisions are recognized in the balance sheet under other current and long-term liabilities.

### **Liabilities**

Financial liabilities are measured at fair value less any transaction costs. After the date of acquisition, loans are measured at amortized cost using the effective interest method. Long-term liabilities have an anticipated life of more than one year while current liabilities mature within one year.

### **Accounts payable**

Accounts payable are classified as other financial liabilities. Accounts payable are expected to be short-term. They are valued at fair value without discounting.

### **Taxes**

Taxes recognized in the income statement consist of current tax and deferred tax. Current tax is tax to be paid or received in the current year. Deferred tax is calculated according to the balance sheet method based on temporary differences between the carrying amount and the tax base of assets and liabilities, applying the tax rates and tax rules that have been set or announced as of the balance sheet date. The amounts are calculated based the tax rates and tax rules that have been established or essentially established as of the balance sheet date.

Temporary differences arise when the carrying amount of holdings in subsidiaries differs from the acquisition cost. Temporary differences are not taken into account in the case of goodwill on consolidation, nor in differences attributable to participations in subsidiaries that are not expected to be taxed in the foreseeable future. In the consolidated accounts, however, untaxed reserves are divided between deferred tax liabilities and equity. Deferred tax liabilities are recognized for all taxable differences relating to holdings in subsidiaries, except where the parent company can control the date of the reversal of the temporary differences and it is not likely that such a reversal will take place in the foreseeable future. Deferred tax assets relating to deductible temporary differences and loss carry-forwards are reported to the extent it is likely that they will be able to be utilized. The value of deferred tax assets is reduced when it is no longer considered likely that they can be utilized.

### **Employee benefits**

Biovitrum offers pension plans to all of its employees and uses both defined contribution and defined benefit plans. The CEO and senior executives are mainly covered by defined contribution plans. For other employees, both defined contribution and defined benefit plans are used.

Pension costs relating to defined contribution plans are charged to earnings as and when the employees perform their duties. Pension commitments are calculated without discounting, as payments for all such plans fall due within a twelve month period.

In the case of defined contribution plans, the company pays fixed contributions to a separate legal entity and there is no obligation to make addition contributions. The Group's earnings are charged with the costs as and when the benefits are earned.

In the case of defined benefit plans, the amount of the pension is determined as a portion of the pensionable final salary, taking into account the number of years of service and average salary at the time of retirement. The Group bears the risk and is responsible for ensuring that the established benefits are paid out.

Biovitrum primarily has defined benefit pension commitments and these commitments are insured through Skandia, Alecta and two pension funds. Pension commitments in Alecta are accounted for as defined benefit pension commitments.

The net amount of the estimated present value of the commitments and fair value of the plan assets is reported in the balance sheet as either a provision or a long-term financial receivable. In cases where it is not possible to fully utilize a surplus in a plan, only the portion of the surplus that can be recovered by the company through reduced future charges or repayments is reported.

Regarding defined benefit plans, pension costs and pension commitments are calculated according to the Projected Unit Credit Method. This method allocates costs for pensions as and when employees perform services for the company that increase the employees' right to receive future remuneration. This calculation is performed annually by independent actuaries. The company's commitments have been valued at the present value of expected future payments by applying a discount rate equivalent to the interest on first-class corporate bonds or government bonds with a duration equivalent to the commitments in question. The most important actuarial assumptions are described in Note 33.

Actuarial gains and losses may arise in connection with the determination of the present value of the commitments and the fair value of the plan asset. Such gains or losses arise either because the actual outcome differs from the previous assumption, or the assumptions have changed. The portion of the accumulated actuarial gains and losses at the end of the previous year that exceeds 10 percent of the greater of the present value of the commitments or the fair value of the plan assets is recognized in the income statement over the employees' average remaining period of service.

Interest expenses, less the anticipated yield on plan assets, are classified as financial expenses. Other expense items in the pension costs are charged to operating profit.

The accounting principle for defined benefit pension plans described above applies only to the consolidated accounts.

Commitments for retirement pensions and family pensions for white-collar employees in Sweden are insured through Alecta. According to statement UFR 3 issued by Swedish Financial Reporting Board, these are defined benefit plans covering multiple employers. For the financial years 2005 – 2009, the company did not have access to the information necessary to be able to report this plan as a defined benefit plan. The ITP pension plan insured through Alecta is therefore reported as a defined contribution plan.

A special payroll tax is calculated primarily on the premiums paid to Alecta, Collectum and Skandia. The special payroll tax is not calculated on non-deductible pension expenses and is expensed over the course of the year.

The anticipated outcome of variable salary for the Group is reconciled on a regular basis throughout the year and the reserves are adjusted on a monthly basis. At the end of each reporting period, an assessment is made of the outcome.

In order to attract and keep competent employees, Biovitrum has established long-term incentive programs. The value of the options is calculated at the time of allocation. The company reports a payroll cost and social security expenses for the services performed by the employees. The costs are distributed on a straight-line basis over the term of the options. A more detailed description of the program can be found in Note 14, Employees, personnel costs and remuneration to the Board.

#### *Remuneration in connection with terminated employment*

A provision is reported in connection with termination only if the company is demonstrably obliged to terminate a position before the normal period of service has ended or when remuneration is offered in order to encourage voluntary resignation, e.g. retirement packages. In cases where the company terminates employment, a detailed plan is drawn up that, as a minimum, contains information on the workplace, positions and approximate number of individuals involved, as well as the remuneration due to each employee category or position and the schedule for the plan's implementation.

#### **Contingent liabilities**

Contingent liabilities are reported when there is a possible commitment arising from events that have occurred and whose existence is based on the occurrence of one or more uncertain future events, or where there is a commitment which is not reported as a liability or a provision due to the fact that it is unlikely that an outflow of resources will be required.

### Parent company's accounting principles

The annual report for Biovitrum AB (publ), the parent company, has been prepared according to the Swedish Annual Accounts Act, the Swedish Financial Reporting Board's recommendation RFR 2.2 Accounting for Legal Entities and statements from the Financial Reporting Board. The parent company applies the same accounting principles as the Group with the following exceptions:

#### *Employee benefits/defined benefit plans*

When calculating defined benefit pension plans, the parent company complies with the Swedish law safeguarding pensions and the Swedish Financial Supervisory Authority's instructions, as compliance with these is a prerequisite for exercising the right to tax deductions. The parent company also complies with FAR's recommendation redR4. The most important differences in comparison with the provisions in IAS 19 are the way in which the discount rate is established, that the defined benefit commitment is calculated according to the current salary level without assumptions on future salary increases, and that actuarial gains and losses are reported in the income statement as they arise.

#### *Leased assets*

All of the parent company's leases are reported according to the rule for operating leases.

#### *Taxes*

For legal entities, untaxed reserves including deferred tax liabilities are reported.

### Basis for preparation of the parent company's and the consolidated financial statements

The parent company's functional currency is the Swedish krona (SEK) which is also the reporting currency for the parent company and the Group. The financial statements are consequently presented in SEK.

All amounts are reported in thousands of SEK unless otherwise indicated. Assets and liabilities are stated at historical cost, except certain financial assets and liabilities which are stated at fair value.

In order to prepare the financial reports in accordance with generally accepted accounting principles, the Board of Directors and management make estimations and assumptions that affect the company's results and financial position as well as other information submitted. These estimations and assumptions are based on historical experience and are regularly reviewed.

Assessments made by management in conjunction with the implementation of IFRS that have a significant influence on the financial reports and estimations made have not involved any significant adjustments in the financial reports of the subsequent year. The accounting principles stated above are used consistently in the preparation of the financial reports that are published and are based on IFRS/IAS.

The stated amounts and figures in parenthesis are comparative figures from 2008.

## Note 3 Financial risk management

### Risk and risk management

Through its operations, the Group is exposed to various kinds of financial risks. The operations are affected by several factors that may impact the company's results and financial position. Biovitrum's strategy includes continuously identifying and managing risk to the greatest extent possible. The risks can be divided into operational risks and financial risks. Below is a description of the financial risk factors that are deemed the most significant for Biovitrum's development and how the company manages them to minimize the level of risk. Operational risk is also described in a separate section in the Director's Report.

### Financial risks and policies

Financial risk relates to fluctuations in the company's profits and cash flow as a result of changes in exchange rates, interest rates and credit exposure. Biovitrum has a comprehensive finance policy that establishes the division of responsibility regarding financial issues between the Board of Directors, the CEO, the CFO, the central finance department and other Group companies. The Board has appointed an Audit Committee to supervise the structure and content of the finance policy and, if necessary, suggest changes to the Board. The finance policy emphasizes a low level of risk. The aim is to minimize the Group's cost of capital by effectively managing and controlling the Group's financial risks.

## Market risk

### Currency risk

#### Transaction exposure

In its operations, the company is also exposed to currency risk. Most of the costs are in Swedish kronor, while a significant portion of the revenues are in other currencies. Due to the international expansion resulting from the sales of Kepivance® and Kineret®, the company's revenues will be generated in additional currencies, while the royalty agreement regarding Pfizer's global sales of ReFacto® and ReFacto AF® /Xyntha® is based on sales primarily in US dollars and euro. Consequently, a drop in the US dollar and euro or other foreign currencies in which revenues are generated in relation to the Swedish krona will have a negative impact on Biovitrum's earnings and financial position.

To hedge future foreign currency flows, the company has adopted the following finance policy with respect to currency hedging:

- Based on forecasts, natural hedging (offsetting/netting of incoming and outgoing currency flows) will be applied as far as possible.
- Biovitrum will hedge the net exposure of foreign currency as follows:

Currency flow	Expected maturity	Hedge ratio	Minimum amount
Known/Secure	< 1 year	80-100 %	SEK 1 million
Known/Secure	1-2 year	25-75 %	SEK 1 million
Known/Secure	2-3 year	0-50 %	SEK 1 million

#### Translation exposure

The Group's results are affected by exchange rate fluctuation when the foreign subsidiaries' results are translated into SEK. Since in 2009 the foreign subsidiaries only made up a minor portion of the Group's operations, this risk was not hedged.

The Group's shareholders' equity is affected by exchange rate fluctuation when the foreign subsidiaries' assets and liabilities are translated to SEK. Hedging of this exposure is assessed from case to case and there are currently no hedges in place.

### Interest risk

Biovitrum's financial management policy is to limit the short-term effects on the Group's results and cash flow due to changes and movement on the financial markets. Interest risk consists partly of changes in fair value (price risk) and partly of changes in cash flow (cash-flow risk). Fixing interest rates mainly affects cash flow risk. The duration of fixed interest rates for the Group's assets and liabilities is usually short. The Board may decide to extend the duration of fixed interest rates in order to limit the impact of increased interest rates.

### Credit risk

Biovitrum's financial transactions give rise to credit risk relating to financial counterparties. The risk of a counterparty not fulfilling its obligations is limited partly by the Group choosing counterparties with a good credit rating and partly by limiting the size of the counterparty's obligations.

### Liquidity risk

Liquidity risk relates to the risk that the Group will not secure sufficient financing or that the cost of financing will increase significantly. Biovitrum's finance policy aims to, as far as possible, reduce the Group's external borrowing by coordinating the management of surplus liquidity within the Group. Investments should only be made in instruments with low credit risk and a high level of liquidity. Investments should only be made in the Swedish Government and in banks, financial institutes and enterprises assigned a credit rating of at least A- by independent evaluators. A high level of liquidity means that the investments can be converted into liquid funds at any given time. Investments are divided between one short-term and one medium to long-term portfolio with a maximum average duration of 2 and 5 years respectively.

The table below shows the Group's financial derivative instruments which will be settled gross, divided according to time which remains between the balance date and due date. The amounts specified in the table are the agreed undiscounted cash flows.

#### Currency forward contracts

As per December 31, 2009	Within 3 months	Between 4 to 6 months	Between 7 to 9 months	Between 10 to 12 months
- outflow	-	-	-	-
- inflow	-	-	-	-

As per December 31, 2008	Within 3 months	Between 4 to 6 months	Between 7 to 9 months	Between 10 to 12 months
- outflow	7,753	7,753	-	-
- inflow	6,092	6,173	-	-

The table below shows when the loans mature:

#### Loan maturity

As per december 31, 2009	Less than 1 year	1-2 year	2-5 year	More than 5 year
Other liabilities - long term	56,058	55,168	163,725	91,956
Accounts payable	243,899	-	-	-
Other liabilities	454,643	-	-	-

As per december 31, 2008	Less than 1 year	1-2 year	2-5 year	More than 5 year
Other liabilities - long term	66,465	64,315	172,915	152,828
Derivatives	3,260	-	-	-
Accounts payable	143,918	-	-	-
Other liabilities	12,520	-	-	-

#### Capital risk

The Group's goal regarding capital structure is to secure the Group's ability to continue its business, so that it can continue to generate earnings to its shareholders and benefits to other stakeholders, and retain an optimal capital structure in order to keep costs of capital down.

The Group's capital is based on the Group's equity ratio. It is the Group's goal to have an equity ratio of at least 40 percent, which also has the support of the main creditors. The equity ratio has decreased compared to previous years. The decrease is mainly attributed to acquisition of products and restructuring expenses during 2008.

Equity ratio as of December 31, 2009 was as follows:

	2009	2008
Shareholders equity	1,352,795	1,284,984
Total assets	2,805,530	2,578,815
Equity ratio	48.2%	49.8%

#### Note 4 Important estimations and assumptions for accounting purposes

The Group makes estimations and assumptions about the future. The resulting estimations for accounting purposes, by definition, seldom correspond fully to actual results. The estimations and assumptions that involve a high risk of significant adjustments in the reported amounts of assets and liabilities for the coming financial year are discussed below.

##### Impairment testing of acquired R&D and other intangible assets

When calculating future cash flows for acquired projects for the company's testing of impairment of acquired R&D, assumptions have been made regarding circumstances in the future and key figures have been estimated.

The key parameters for impairment testing include future cash flow, the probability of realizing a positive outcome in clinical studies and the assumption of best commercial outcome. Future cash flow is estimated in terms of the project's progress in the short and long term and adjusted for the probability that the combined costs and earnings



are realized. The earlier the phase of development of a project, the higher the risk. The possibility of reaching the market improves at the rate the project completes the pre-defined phases of development. An assessment of the probability that a project will successfully complete a certain phase of development is made based on the scientific potential that the project can reach a positive outcome in the individual phase of the development process. A best case assumption is made using parameters that affect the project's development into a pharmaceutical with the highest possible commercial potential based on what is reasonable to assume of the project's scientific profile given the information available today. The forecast period is based on the product's estimated useful life on the market.

#### Acquired R&D and other intangible assets

The milestones to Amgen shown in the table below with respect to the accumulated sales that Kineret® and Kepivance® are expected to be reached, and have therefore been included in the purchase price. The actual outcome is based on future sales forecasts.

#### Milestone payments

Product	Amount USD thousands	Book value SEK thousands	Estimated to be paid
Kineret	10,000	66,684	2011
Kineret	20,000	123,305	2013
Kepivance	10,000	61,653	2013
Kepivance	20,000	114,003	2015
	<b>60,000</b>	<b>365,645</b>	

At present value calculation, the estimated percentage rate is 4 percent. Interest is based on a 5-year risk-free interest with a risk premium added. See note 39 "Significant events after the balance sheet date" regarding advance buy-out of previously agreed future sales milestones.

#### Assumptions for the calculation of pension benefits

The actuarial calculations of pension commitments and pension costs are based on actuarial assumptions as specified in Note 2 and Note 33.

#### Inventory

##### Indirect production costs

Costs for production consist of direct production costs such as raw materials, consumables, media and manpower, as well as indirect costs such as personnel costs, depreciation, maintenance, etc.

Indirect cost calculations are based on a method for calculating standard costs. This method is revised on a regular basis to ensure a reasonable calculation of the degree of usage, lead times and other relevant factors. Changes in the method of calculating the indirect production costs, including the degree of usage, lead times, etc. may have an impact on gross margins and the overall valuation of inventories.

##### Obsolescence

Inventory consists of drug substance and drug product for Kepivance®, Stemgen® och Kineret®. For this inventory no provision for obsolescence is made. Vials not approved will be directly expensed.

Other stock mainly consists of ReFacto®, and consists of biological cultures with a risk of defective components. The production of ReFacto® takes place in two stages: cultivation and purification. If a certain portion of the stock is not approved by the quality department of Biovitrum and/or Pfizer, Biovitrum will do an obsolescence assessment of the batch that was not approved, based on historical obsolescence. Biovitrum is part of the pharmacological industry, which is regulated and controlled by several authorities in and outside Sweden. Also, the company collaborates with external partners, both Swedish and foreign, who controls and evaluates the business.

#### Revenues

The Group assesses the likelihood of future economic benefits accruing to the Group on the basis of a number of factors, including a customer's payment history and credit rating. On certain occasions, the Group requests payment in advance in the form of a signing fee from customers. If a receivable is deemed doubtful by the Group, a provision is made for the receivable until it is possible to determine whether the Group will receive payment or not. According to the Group's routine for advances, advanced payments are recognized as other current liabilities until they are earned. The Group also recognizes deferred revenue from licensing agreements. According to the

milestone method, successive milestones are considered as separate from the initial licensing fee. The initial licensing fee is distributed over the expected life of the contract because, when it is received, no separate earning period is deemed to have been completed. Subsequent milestones, however, are considered to belong to a particular completed portion of the contract. This portion should therefore be able to be recognized as revenue as soon as it is received, i.e. when the terms of the underlying agreement have been met.

In September 2003, Biovitrum entered into a Development and Marketing Collaboration Agreement with Amgen. This agreement is very complex and contains a number of components that are delivered at different times. On signing the agreement, Biovitrum received a large sum in the form of an initial licensing fee. Biovitrum may also receive a number of milestone payments during the development period. The company estimates the vesting period to be five years based on the project and the structure of the agreement. The effect on earnings during the previous financial year, 2008, and until the end of the third quarter was SEK 132 M. This means that the entire original payment of SEK 711 M has been taken up as revenue.

### **Taxes**

The Group's deferred tax receivables have been recognized based on the assumption that it will be possible to utilize them to reduce future tax payments. Deferred tax is calculated according to the balance sheet method based on temporary differences between reported amounts and the written down value of assets and liabilities. The amounts are calculated using the tax rates that apply or have been announced as of the balance sheet date. The parent company and one Swedish subsidiary report tax loss carry-forwards. In accordance with current tax regulations, these never mature. Deferred tax assets are only reported for these tax loss carry-forwards when it is deemed probable that the Group will utilize them against future taxable profits.

### **Leases/Rent**

Biovitrum applies IAS 17 Leases. The lease agreements in the consolidated accounts are either classified as finance or operating leases. Leased fixed assets where Biovitrum is responsible for the same risks and benefits as in the case of direct ownership are classified as finance leases. All other classifications are considered operating leases.

Biovitrum AB (publ) sold properties through its subsidiaries in 2004 and 2005. Hornsberg 10 was sold in 2005 to Index Real Estate and Paradiset 12 – 14 was sold in 2004 to Guldskålen J 301 AB, after which Biovitrum entered into lease agreements for the same properties.

In cases where a property is part of a sale-and-lease-back deal, an assessment is made of which company carries the most significant risks and benefits related to the property, and whether the Group continues to have a significant obligation with respect to the sold property.

Contracts regarding land that is not transferred to the lessee upon expiry of the lease contract are regarded as operating leases. In this case, the right of ownership of the land is not transferred to Biovitrum at the end of the lease period and accordingly, no calculation is made of this portion of the minimum lease charges.

Minimum lease charges are, in this case, the rent established in the lease contract. Variable fees, possible service fees and taxes are not included. The distribution of minimum lease charges between land and buildings is to be based on the fair value of the respective asset, according to IAS 17. The company has used the property's taxable value as a basis for distribution in order to divide the minimum lease charges between buildings and land.

The company has assessed the present value of future minimum lease charges in relation to the selling price indicated in the property sale agreements of 2004 and 2005. See Note 12.

### **Research and development costs**

The company conducts research and development in internal projects as well as with external partners. In cases where the company runs projects with an external partner and both parties share certain costs, an assessment is made of costs in connection with the start of the project. This cost is then used as a basis for deductions reconciled with the external partner. The calculation is assessed and updated regularly.

In certain partnership agreements, the company agrees to pay a milestone payment. This payment is carried forward as research and development and amortization only starts when the project has reached the commercialization phase. Evaluation of the project's progress and impairment testing are carried out regularly, at least once a year.

Expenses for internal R&D projects are expensed at the time they occur if they do not fulfill the requirements of IAS 38 Intangible Assets. Standards and uncertainty usually mean that the criteria are not fulfilled. In cases where all the criteria are fulfilled, however, the intangible assets are capitalized and amortized on a straight-line basis

from the time the company can prove that it is technically possible to fulfill and profitably commercialize the results.

Payments concerning the projects and substances in agreements with third parties, which are generally defined as prepaid payment and conditional payments, are capitalized and amortized on a straight-line basis from the time the product can be commercialized.

## Note 5 Acquired operations after the end of the year

On November 5, 2009 Biovitrum's acquisition of Swedish Orphan and the creation of a new specialist pharmaceutical company aimed at rare diseases was announced. The transaction is based on commercial benefits and profitable future growth. The acquisition was concluded on January 14, 2010.

Below is a preliminary acquisition analysis of the acquisition of Swedish Orphan.

<b>Purchase price allocation</b>		
<i>Amounts in SEK million</i>		
<b>Purchase price</b>		
- cash payment	1,923.0	
- discounted value est. future additional purchase price	165.0	
- direct cost related to the acquisition	33.0	
- fair value of shares issued	1,739.0	
<b>Total purchase price</b>	<b>3,860.0</b>	
Book value acquired net assets	-456.0	
<b>Total adjustment in purchase price allocation</b>	<b>3,404.0</b>	

<b>Assets and liabilities in acquired operation</b>		
<i>Amounts in SEK million</i>		
	Fair value	Acquired book value
Goodwill	—	213.0
Other intangible assets	2,680.0	37.0
Tangible assets	14.0	14.0
Financial fixed assets	3.0	3.0
Deferred income tax receivables	—	—
Other current assets	449.0	449.0
<b>Total assets in acquired operation</b>	<b>3,146.0</b>	<b>716.0</b>
Long-term borrowings	31.0	31.0
Retirement benefit obligations	3.0	3.0
Deferred income tax liabilities	749.0	44.0
Current liabilities	182.0	182.0
<b>Total liabilities in acquired operation</b>	<b>965.0</b>	<b>260.0</b>
<b>Acquired net assets</b>	<b>2,181.0</b>	<b>456.0</b>
Goodwill	1,679.0	—
<b>Total purchase sum</b>	<b>3,860.0</b>	<b>456.0</b>

Goodwill pertains to the established legal structure and market presence in most countries and the synergy effects that are expected to arise by coordinating the operations of Biovitrum and Swedish Orphan.

The estimated value of the capital contributed in kind is equivalent to a subscription price of around SEK 29.80 per ordinary share, representing a volume-weighted average price for the Biovitrum share during the 20 trading days preceding the announcement of the acquisition on November 5, 2009 adjusted for dilution of the rights issue that Biovitrum implemented to partially finance the cash payment for the acquisition.

The fair value of the acquired identifiable intangible assets of SEK 2,680 Million is a preliminary figure pending the receipt of a final measurement of these assets, and also the final valuation of the additional purchase price.

<b>Liquid funds</b>	
<i>Amounts in SEK million</i>	
<b>Liquid funds</b>	
- cash payment	-1,923.0
Paid acquisition costs	-33.0
Liquid funds in acquired operation	122.0
<b>Effect on liquid funds</b>	<b>-1,834.0</b>

The acquisition agreement includes e.g. an undertaking by former CEO of Swedish Orphan, Bo Jesper Hansen, not to compete with Biovitrum or its subsidiaries during a period of three years from completion of the transaction. For this undertaking, Bo Jesper Hansen is, under the relevant three-year period, entitled to a monthly compensation amounting to approximately DKK 565,000, however reduced with e.g. any compensation payable to Bo Jesper Hansen during the same period by Biovitrum or any group company under any employment or consultancy arrangement.

## Note 6 Distribution of revenues

Group	2009	2008
<i>Total revenues by major type of income</i>		
Licensing and Milestone Revenues	62,616	132,535
ReFacto® manufacturing revenues	362,459	569,330
Contract Development revenues	14,058	49,631
Co-promotion revenues	127,308	174,660
Royalty revenues	165,650	176,218
Product sales	564,780	38,209
Other	102	–
	1,296,973	1,140,583
<b>Parent Company</b>		
<i>Total revenues by major type of income</i>		
Licensing and Milestone Revenues	62,616	132,535
ReFacto® manufacturing revenues	362,459	569,330
Contract Development revenues	14,058	49,631
Co-promotion revenues	127,308	174,660
Royalty revenues	165,650	176,218
Product sales	564,780	38,209
Other	83	–
	1,296,954	1,140,583

## Note 7 Segment reporting

On January 1, 2009 the Group implemented IFRS 8 Operating Segments, which replaces IAS 14, Segment Reporting. The new standard requires segment information to be presented from the management's perspective, which means presented on the same basis that is used for internal reporting. The basis for identifying reportable segments is the internal reporting as reported to and followed up by the highest decision-making executive. For Biovitrum, this is the Group's CEO. Following the introduction of IFRS 8, the Group has not identified any new operating segments compared to those in the past. In connection with the acquisition of products from Amgen in December 2008, Biovitrum has sales in a number of geographical areas. From 2009, Biovitrum is therefore reporting revenues by geographical area.

Group	2009	2008
Europe	982,877	911,985
North America	259,981	156,583
Other	54,115	72,015
<b>Total revenues</b>	<b>1,296,973</b>	<b>1,140,583</b>
<b>Parent Company</b>		
Europe	982,858	911,985
North America	259,981	156,583
Other	54,115	72,015
<b>Total revenues</b>	<b>1,296,954</b>	<b>1,140,583</b>

## Note 8 Cost of goods and services sold

Group	2009	2008
Cost of goods sold	-375,740	-186,123
Cost of contract development services sold	–	-78,540
	-375,740	-264,663
<b>Parent Company</b>		
Cost of goods sold	-375,740	-186,125
Cost of contract development services sold	–	-78,540
	-375,740	-264,665

## Note 9 Depreciation/amortization and write-down of intangible and tangible fixed assets

Group	2009	2008
<i>Depreciation according to plan by type of asset</i>		
Capitalized software expenses	-2,527	-5,369
Patents and licenses	-49,297	-631
Plant and machinery	-29,339	-38,315
Equipment, tools, fixtures and fittings	-28,501	-25,018
	-109,664	-69,333
<i>Depreciation according to plan by function</i>		
Cost of goods and services sold	-30,242	-32,193
Sales and marketing expenses	-978	-631
Administration expenses	-51,293	-2,197
Research and development expenses	-27,151	-34,312
	-109,664	-69,333
<i>Write-downs by type of asset</i>		
Patents and licenses	–	-173,293
Plant and machinery	–	-7,150
Equipment, tools, fixtures and fittings	–	-17,731
	–	-198,174
<i>Write-downs by function <sup>1</sup></i>		
Administration expenses	–	-53,197
Research and development expenses	–	-144,977
	–	-198,174

<sup>1</sup> SEK 198 174 thousands is included in "Restructuring expenses" in income statement for 2008.

Parent Company	2009	2008
<i>Depreciation according to plan by type of asset</i>		
Capitalized software expenses	-2,527	-5,369
Patents and licenses	-49,297	-631
Plant and machinery	-29,339	-37,855
Equipment, tools, fixtures and fittings	-26,411	-22,252
	-107,574	-66,107
<i>Depreciation according to plan by function</i>		
Cost of goods and services sold	-30,242	-32,193
Sales and marketing expenses	-978	-631
Administration expenses	-51,293	-2,197
Research and development expenses	-25,061	-31,086
	-107,574	-66,107
<i>Write-downs by type of asset</i>		
Sales and marketing expenses	–	-28,316
Research and development expenses	–	-7,150
Equipment, tools, fixtures and fittings	–	-17,731
	–	-53,197
<i>Write-downs by function <sup>1)</sup></i>		
Administration expenses	–	-53,197
	–	-53,197

<sup>1)</sup> SEK 53 197 thousands is included in "Restructuring expenses" in income statement for 2008.

## Note 10 Other operating revenues

Group	2009	2008
Rental income	2,445	2,038
Exchange rate gains on operating receivables/liabilities	38,311	29,165
Result from cash flow hedging	266	2,147
Gain on sale of fixed assets	2,095	50
Contribution received	128	740
Other	17	158
	43,262	34,298

Parent Company	2009	2008
Rental income	2,445	2,038
Exchange rate gains on operating receivables/liabilities	38,259	29,165
Result from cash flow hedging	266	2,147
Gain on sale of fixed assets	2,095	50
Contribution received	128	740
Other	7	636
	43,200	34,776

## Note 11 Other operating expenses

Group	2009	2008
Exchange rate losses on operating receivables/liabilities	-49,199	-10,615
Restructuring costs	–	-1,201
Capital loss divestment of operation	-26,956	–
Reimbursed foreign VAT	822	273
Other	-665	-189
	-75,998	-11,732

Parent Company	2009	2008
Exchange rate losses on operating receivables/liabilities	-49,160	-10,615
Scrapping costs	–	-1,201
Reimbursed foreign VAT	822	273
	-48,338	-11,543

## Note 12 Expenses for operational leasing

Contractual future lease charges for non-cancellable contracts fall due for payment as follows:

	Group		Parent company	
	2009	2008	2009	2008
Within 1 year	4,710	7,094	4,710	7,094
Between 1 and 5 years	3,713	11,205	3,713	11,205
	8,423	18,299	8,423	18,299

Leasing costs for the year: 6,539 4,735 6,534 4,687

Contractual future rental costs for premises with non-cancellable contracts fall due for payment as follows:

	Group		Parent company	
	2009	2008	2009	2008
Within 1 year	85,747	76,599	85,747	72,497
Between 1 and 5 years	320,998	381,019	320,998	377,322
Later than 5 years	899,599	1,031,029	899,599	1,031,029
	1,306,344	1,488,647	1,306,344	1,480,848

Leasing costs for the year: 69,595 104,160 64,176 96,930

In 2009 Biovitrum entered into lease agreements regarding equipment with Swedbank Finans. The total contract cost for these agreements is SEK 2,123 thousands.

The decisive factor in the classification of leases is to what extent the economic risks and benefits associated with ownership of the leased object are retained by the lessor or transferred to the lessee. As regards properties, assessments of the lease agreement must be made both for the building and the land.

Biovitrum bases its position mainly on the fact that the present value of minimum lease charges does not constitute a significant portion of the fair value of the property and that there are otherwise no significant indications that a finance lease exists.

Biovitrum subleases parts of its premises in Gothenburg. This agreement is considered an operating lease and rental income is recognized over the term of the lease.

### Note 13 Results from participation in Group companies

Parent company	2009	2008
Result from limited partnership	-75	–
Capital gain from divestment of subsidiaries	23,112	–
Write-down of shares in subsidiaries	-5,412	-168,461
	17,625	-168,461

### Note 14 Personnel, personnel costs and remuneration to Board and executive management

#### Average number of employees

	2009	of which men	2008	of which men
<b>Group and Parent Company</b>				
Sweden	403	41%	453	43%
Denmark	1	–	1	–
Finland	2	100%	3	100%
Norway	2	100%	2	100%
United Kingdom	25	57%	26	63%
Total	433	42%	485	45%

#### Salaries, other remuneration and social security expenses

	2009		2008	
<b>Group and Parent Company</b>	Salaries and remunerations	Social security costs	Salaries and remunerations	Social security costs
Parent Company	237,013	135,765	288,265	170,429
of which pension cost <sup>1</sup>		(54,024)		(62,030)
Subsidiary	13,325	2,302	20,257	2,349
of which pension cost <sup>1</sup>		(782)		(747)
Group total	250,338	138,067	308,522	172,778
of which pension cost <sup>1</sup>		(54,806)		(62,777)

<sup>1</sup> Of the Group's and Parent Company's pensions costs, SEK 1,478 thousand (1,453) pertain to the Board and CEO.  
The Group's outstanding pension commitments for the Board and CEO amount to SEK 0 thousand (0).

#### Salaries and other remuneration by country and among Board members etc. and other employees

	2009		2008	
<b>Parent Company</b>	Board and CEO	Other employees	Board and CEO	Other employees
Sweden	14,059	216,609	14,162	268,916
(of which bonuses, etc.)	(2,382)	(14,035)	(1,738)	(11,422)
Denmark	–	1,356	–	976
Finland	–	2,652	–	2,241
Norway	–	2,337	–	1,970
Parent company total	14,059	222,954	14,162	274,103
(of which bonuses, etc.)	(2,382)	(14,035)	(1,738)	(11,422)
<b>Subsidiaries outside Sweden</b>				
United Kingdom	1,895	11,429	3,236	17,021
(of which bonuses, etc.)	(–)	(70)	(943)	(886)
<b>Subsidiary total</b>	1,895	11,429	3,236	17,021
<b>Group total</b>	15,954	234,383	17,398	291,124
(of which bonuses, etc.)	(2,382)	(14,105)	(2,681)	(12,308)

### **Guidelines for remuneration to senior executives**

The full guidelines are described in the Directors' Report.

### **Remuneration to the CEO**

Martin Nicklasson took up the position as Chief Executive Officer on May 14, 2007.

In 2009 Martin Nicklasson received a salary of SEK 4,765 thousands (4,636) in fixed salary. The CEO's salary is reviewed annually on January 1 by the Board and the company's Compensation & Benefits Committee. Besides fixed salary, a variable salary of no more than 50 percent of the fixed annual cash salary (basic salary) is paid. The variable salary adheres to a system approved by the Board and is based on comprehensive company objectives. The 2009 variable salary amounted to SEK 2,382 thousands (1,738).

Biovitrum pays a contribution of 30 percent of pensionable salary for Martin Nicklasson's future pension benefits. Pensionable salary in 2009 was SEK 4,765 thousands annually and the retirement age is 65.

Martin Nicklasson has a notice period of six months if notice is given by Biovitrum and six months if he resigns. If notice is given by Biovitrum, severance pay equal to 18 monthly salaries can be paid. However, the severance pay cannot exceed the current salary for as many months as remain until the normal retirement age.

Martin Nicklasson participates in three of Biovitrum's long-term incentive programs. He holds 300,000 employee options in option program 2007/2012 and is entitled to hold no more than 94,589 shares in Share Program 2008 and 53,239 shares in Share Program 2009. At year-end, Martin Nicklasson held 10,000 Biovitrum shares.

### **Fixed and variable salaries**

The CEO, executive management, managers, and a number of key employees receive a variable salary in addition to their fixed salary. The variable portion is in line with a system approved by the Board and is based on company objectives and individual goals.

Variable salaries for the CEO and executive management are based 100 percent on company objectives. The individual levels are maximum between 30 and 50 percent of basic salary.

For other executives and key employees, the variable salary is based 30 percent on company objectives and 70 percent on individual goals. Variable salary levels for these individuals are between 5 and 30 percent of fixed pay and this is paid annually in cash for the previous year. The variable salary is pensionable income and calculation is based on Alecta's calculation and on a three-year average.

The expected outcome is reconciled regularly throughout the year and reserves are adjusted monthly. On each reporting occasion, an assessment is made of the variable salaries.

### **Pensions for executive management**

Biovitrum's pension plan for executive management is principally a defined contribution plan. This means that Biovitrum makes contributions equal to 27 percent of the employee's pensionable salary into a pension plan set up for the employee. The employee is covered by the ITP plan and the Manager Plan constitutes the alternate ITP. The contribution paid to Alecta is included in the contracted contribution. The pensionable salary is maximized at 50 income base amounts.

In conjunction with the transition from defined benefit to defined contribution plans, individual agreements were reached with percentages exceeding 27 percent. This applies to two individuals who have contributions of 30-35 percent, and in these cases, the contributions paid to Alecta for the ITP plan's basic benefits were excluded and paid in addition to the agreed contribution level.

One person is still covered by the defined benefit Manager Plan. This plan entitles retirement at age 60 with a benefit level as per the ITP plan as well as 32.5 percent in pension on salary portions between 30 and 50 income base amounts. The plan also includes a guarantee of 50 percent in pension if the employee resigns his post after having completed a full period of service by retirement age.



**Remuneration and other benefits for the Board, CEO and other senior executives**

2009	Basic pay/ fees	Variable remuneration	Pension cost	Other benefits	Financial instrument	Other remuneration	Total
Chairman of the Board	983	–	–	–	–	–	983
Other board members							
Mats-Olof Ljungkvist	292	–	–	–	–	–	292
Anders Hultin <sup>1</sup>	92	–	–	–	–	–	92
Wenche Rolfsen	275	–	–	–	–	–	275
Michael Steinmetz	300	–	–	–	–	–	300
Toni Weitzberg <sup>1</sup>	83	–	–	–	–	–	83
Hans Wigzell	275	–	–	–	–	–	275
Hans Glemstedt	167	–	–	–	–	–	167
Peter Sellei	200	–	–	–	–	–	200
Chief Executive Officer							
Martin Nicklasson	4,765	2,382	1,478	233	2,534	–	11,392
Other senior management <sup>2</sup>	11,939	4,000	5,977	177	2,928	381	25,402
	19,371	6,382	7,455	410	5,462	381	39,461
2008	Basic pay/ fees	Variable remuneration	Pension cost	Other benefits	Financial instrument	Other remuneration	Total
Chairman of the Board	825	–	–	–	–	–	825
Other board members							
Mats-Olof Ljungkvist	300	–	–	–	–	–	300
Anders Hultin	275	–	–	–	–	–	275
Wenche Rolfsen	275	–	–	–	–	–	275
Michael Steinmetz	300	–	–	–	–	–	300
Toni Weitzberg	250	–	–	–	–	–	250
Hans Wigzell	275	–	–	–	–	–	275
Chief Executive Officer							
Martin Nicklasson	4,636	1,738	1,453	221	3,614	–	11,662
Other senior management <sup>2</sup>	12,237	3,776	7,987	149	41	589	24,779
	19,373	5,514	9,440	370	3,655	589	38,941

<sup>1</sup> Anders Hultin and Toni Weitzberg were members of the board of directors during 2008. The remuneration refers to work carried out during this period.

<sup>2</sup> Other senior management refers to Biovitrum's management group in which 7 (9) individuals, excluding the Managing director, are included.

During the first 5 months of 2008, the management group consisted of 9+1 employees and, during the remaining part of the year, 6+1 employees.

**Remuneration and other benefits for the Board, CEO and other senior executives – Parent company and subsidiaries**

	2009	2008
<b>Parent Company</b>		
Salaries and remunerations	32,006	29,501
(of which bonuses etc)	(6,382)	(5,514)
Pension cost	7,455	9,440
Number of persons (excl. union representatives)	17	15
<b>Subsidiaries</b>		
Salaries and remunerations	1,809	3,146
(of which bonuses etc)	–	(943)
Pension cost	87	90
Number of persons	1	1
<b>Group</b>		
Salaries and remunerations	33,815	32,647
(of which bonuses etc)	(6,382)	(6,457)
Pension cost	7,542	9,530
Number of persons (excl. union representatives)	18	16

## Incentive programs

In order to attract and retain skilled and motivated personnel, Biovitrum has established long-term incentive programs. Below is a description of the share-related programs that are currently in existence.

### **Warrant program 2006/2008 for senior executives**

Before the stock exchange listing in 2006, warrants in an earlier warrant program were repurchased and certain members of Biovitrum's executive management instead subscribed for warrants in a new program. The purpose of the program is to maintain an effective incentive plan for Biovitrum's senior management. The total number of warrants in this program amounts to 2,326,136 and each warrant carries the right to purchase one share. In the program, warrants are divided into four equal tranches with expiry dates of August 31, 2008, November 30, 2008, February 28, 2009 and May 31, 2009, and with a common exercise price of SEK 59 per share. The warrants have an exercise period starting twelve months before each expiry date.

In 2009, 581,534 warrants in Warrant Program 2006/2008 were exercised and 581,534 expired.

<b>Warrants</b>	<b>2009</b>	<b>2008</b>
Outstanding January 1	1 163 068	2 326 136
Allocated during the period	-	-
Exercised during the period	-581 534	-281 144
Expired during the period	-581 534	-881 924
<b>Outstanding as per December 31</b>	<b>0</b>	<b>1 163 068</b>
<b>Redeemable as per December 31</b>	<b>0</b>	<b>1 163 068</b>

The valuation parameters (adjusted after 2:1 split) at the time of issue are the following:

- Share price SEK 70,65
- Exercise price SEK 42,21
- Volatility 30 percent.
- No expected dividends.
- Risk free interest rate 2.69 percent for warrants expiring August 31, 2008.
- Risk free interest rate 2.76 percent for warrants expiring November 30, 2008.
- Risk free interest rate 2.84 percent for warrants expiring February 28, 2009.
- Risk free interest rate 2.91 percent for warrants expiring May 31, 2009.

### **Employee option program 2006/2011**

In May 2006, in addition to the program described above, Biovitrum issued 150,000 warrants, each carrying the right to subscribe for two shares, intended for an employee option program for certain key individuals. After the issue in 2009 each warrant carries the right to subscribe for 3.78 shares. The exercise price for these warrants is SEK 58.21 per share with an exercise period ending on May 31, 2011.

The allocation was carried out following a decision by Biovitrum's Compensation & Benefits Committee. The options were allocated and give the employees the right to earn an equal amount of warrants, with allocation of one third of the total allocated amount per year during the first three years. Employee options and the subsequent warrants are allocated free of charge (without payment). If employment is terminated within this three-year period, the employee forfeits his/her allocated options and the right to the warrants.

In 2009 no new allocations were made within the employee option program 2006/2011.

<b>Warrants</b>	<b>2009</b>	<b>2008</b>
Outstanding January 1	40 000	60 000
Allocated during the period	-	-
Exercised during the period	-	-
Decayed during the period	-5 000	-20 000
<b>Outstanding as per December 31</b>	<b>35 000</b>	<b>40 000</b>
<b>Redeemable as per December 31</b>	<b>35 000</b>	<b>24 998</b>

The cost of the employee option program 2006/2011 is expected to be earned on a straight-line basis, which means that the total amount of allocated options will be expensed at one third per year.

The following valuation parameters were used on the issue date:

	<u>Date of issue</u>	
	May 2006	September 2006
<u>Valuation parameters</u>		
Share price (SEK)	70,65	83,74
Exercise price (SEK)	58,21	58,21
Volatility (%)	30	30
Dividend (SEK)	No expected dividend	No expected dividend
Risk free rate (%)	3,55	3,51
Fair value per warrant (SEK)	29,40	39,70

#### **Employee option program 2007/2012**

At the 2007 Annual General Meeting of shareholders a decision was made to introduce employee option program 2007/2012. Within the framework of this program, employee options can be issued that carry the right to acquire a maximum of 567,000 shares in the company. Each employee option can be exercised until April 1, 2012 to acquire 1.89 shares in Biovitrum for the exercise price of SEK 58.21.

The right to acquire new shares in accordance with the employee options can be used with an allocation of one third one year after the anniversary date of the allocation and an additional one third on each of the two following anniversaries. This is contingent upon the holder, on each occasion, still being an employee of the company and not having been dismissed or given notice from his/her position within the company.

To guarantee that the company can fulfill its obligation to employee option holders when they exercise their options, the Annual General Meeting also decided that 300,000 warrants for the subscription of new shares will be issued to the wholly-owned subsidiary Biovitrum Treasury AB. The company will use the warrants to cover its obligations to the employee option holders when exercising their options.

<b>Warrants</b>	<b>2009</b>	<b>2008</b>
Outstanding January 1	300 000	300 000
Allocated during the period	-	-
Exercised during the period	-	-
Expired during the period	-	-
<b>Outstanding as per December 31</b>	<b>300 000</b>	<b>300 000</b>
<b>Redeemable as per December 31</b>	<b>200 000</b>	<b>100 000</b>

When expensing the employee option program 2007/2012, 100,000 of the allocated warrants are estimated to have an earning rate of one year, a further 100,000 warrants have an earning rate of two years, and the last 100,000 warrants have an earning rate of three years. This means that a proportionally larger share of the costs is reported in the first year of the program.

The following data was used to calculate the cost of the 2007/2012 program at the time of issue:

- Share price SEK 73,06
- Exercise price SEK 58,21
- Volatility 30 percent.
- No expected dividends.
- Risk free interest rate of 3.95 percent

The fair value per option amounts to SEK 30.97.

Biovitrum has selected the Black & Scholes model for valuation of the warrants. When selecting a model, the company has taken into account the same considerations as knowledgeable and interested parties independent of each other would have done. Important factors in the underlying model are the following:

- exercise price
- the life of the option
- current price of the underlying shares
- the shares' expected volatility
- expected dividends, and
- the risk-free interest rate during the life of the option

The expected volatility is a measure of the share price fluctuations over a period of time. Biovitrum has taken the following into account in estimating the expected volatility:

- Implicit volatility for other company instruments that are traded and have the characteristics of warrants.
- Historical volatility of the share price and, since the company was only recently listed, the historical share price development of similar companies. The historical period is the same as the warrants' exercise period.
- The long-term average level of volatility.

#### ***Share Program 2008 and 2009***

At the 2008 Annual General Meeting a decision was made to introduce a performance-based, long-term share program and at the 2009 AGM a decision was made regarding an additional performance-based, long-term share program. The terms and the conditions of the two programs are the same. The programs cover managers and key employees who have the opportunity to be allotted ordinary shares in Biovitrum free of charge. The outcome of Share Program 2008 and 2009 is dependent on the fulfillment of set value creation targets determined by the Board of Directors and linked to the total shareholder return of the Biovitrum ordinary share (the share price development adjusted with respect to dividends), for a three year period from the date of the offer to participate in the program (the "Performance Period"). These targets are designated Performance Condition 1 and Performance Condition 2.

Performance Condition 1: For any allotment of ordinary shares to be possible under Share Program 2008 and Share Program 2009, the total shareholder return for the Biovitrum ordinary share must amount to at least 15% during the Performance Period.

Performance Condition 2: Upon fulfillment of Performance Condition 1, an evaluation is carried out of the total shareholder return for the Biovitrum ordinary share in relation to a group of comparable companies, as established by the Board of Directors. As a condition for the allotment of ordinary shares, it has been established that a minimum level for the total shareholder return of the Biovitrum ordinary share must correspond to the median performance for the comparable group. It has been established that full allotment will be carried out if the total shareholder return for the Biovitrum ordinary share corresponds to the upper quartile for the comparable group (the maximum level) or exceeds this level. If the minimum level is reached, an allotment of 35% of the maximum number of ordinary shares, in accordance with what has been described previously, will be carried out. If the total shareholder return for the Biovitrum ordinary share exceeds the minimum level but falls below the maximum level, a pro rata allotment will be carried out. The allotment of ordinary shares requires that the individuals participating in the program are employed in the Biovitrum Group for the entire Performance Period and have not, at the time of allotment of the gratuitous ordinary shares, terminated their employment. If all conditions in the Share Program 2008 and 2009 are met, allotment of ordinary shares will take place free of charge after the end of the Performance Period.

**Share Program 2008** was implemented at the end of 2008 and the Performance Period will run from November 26, 2008 until November 25, 2011. The program may involve a total maximum allotment of 433,952 shares in Biovitrum AB (publ).

When expensing Share Program 2008, the shares are calculated according to the following parameters:

- Number of shares 433,952
- Vesting period 36 months
- Share price at introduction SEK 22,42
- Expected share price at expiry date SEK 31,00
- Share value (price at expiry - price at introduction) SEK 8,59
- Social security expenses 32.28 percent
- Anticipated turnover of 10% among the relevant employees.

**Share Program 2009** was implemented at the end of 2008 and the performance period will run from June 10, 2009 until June 9, 2012. The program may involve a total maximum allocation of 380,735 shares in Biovitrum. When the share program is carried as an expense 2009, the shares are calculated according to the following parameters.

- Number of shares 380,735
- Vesting period 36 months
- Share price at introduction SEK 30,44
- Expected share price at expiry date SEK 44,32
- Share value (price at expiry - price at introduction) SEK 13,88
- Social security expenses 32.28 percent
- Anticipated turnover of 10% among the relevant employees

### Financial instruments pertaining to employees

	2009	2008
Alloted	1 503 068	2 686 136
Sold	-586 534	—
Repurchased	—	-901 924
Used	-581 534	-281 144
	<u>335 000</u>	<u>1 503 068</u>

### Specification of men and women in the Board and executive management

The data in the table does not include employee representatives and refers to the status as of the balance sheet date.

	Group	
Board	2009	2008
Men	8	6
Women	1	1
	<u>9</u>	<u>7</u>
CEO and executive management		
Men	6	6
Women	2	2

The data in the table does not include employee representatives and refers to the status as of the balance sheet date.

### Absence due to illness

	Parent Company	
	2009	2008
Leave of absence due to illness in relation to ordinary working hours specified according to age and sex:		
29 years and younger	1,30%	1,00%
30-49 years	1,40%	1,70%
50 years and older	1,90%	2,80%
Total leave of absence due to illness in relation to ordinary working hours	1,60%	2,00%
of which:		
men	26,16%	20,35%
women	73,84%	79,66%
Portion of leave of absence due to illness for leave of absence of 60 consecutive days or more	24,80%	32,95%

### Note 15 Remuneration and reimbursement paid to auditors

Group	2009	2008
<i>Öhrlings PricewaterhouseCoopers</i>		
Auditing assignments	3,454	2,104
Other assignments	5,389	16,055
	<u>8,843</u>	<u>18,159</u>
<i>Other auditor</i>		
Auditing assignments	175	191
Parent Company	2009	2008
<i>Öhrlings PricewaterhouseCoopers</i>		
Auditing assignments	3,454	2,104
Other assignments	5,389	16,055
	<u>8,843</u>	<u>18,159</u>

“Auditing assignments” involves auditing of the annual financial statements and the accounts as well as the Board’s and the CEO administration, other duties which are normally performed by the company’s auditor as well as counseling or other support required following observations made in connection with an audit or the performance of other such duties. The “Auditing assignments” category for 2009 included an examination of the prospectus prepared in connection with the acquisition of Swedish Orphan. All other duties are under Other Assignments.

The “Other assignments” category in 2009 included consultation for an amount of SEK 3,862 thousands in connection with adapting the company’s operations following the acquisition of products and licenses from Amgen in December 2008. The “Other assignments” category in 2008 included consultation in connection with the acquisition of products and licenses from Amgen, amounting to SEK 14,281 thousands.

## Note 16 Operating expenses classified by type

Group	2009	2008
Raw materials and consumables	-134,387	-63,607
Other external costs	-601,987	-644,992
Personnel costs	-402,025	-573,237
Depreciation and write-downs	-109,664	-267,508
Other operating expenses	-75,998	-11,732
	-1,324,061	-1,561,076

Parent Company	2009	2008
Raw materials and consumables	-134,387	-63,607
Other external costs	-621,672	-671,653
Personnel costs	-391,782	-553,736
Depreciation and write-downs	-107,573	-119,304
Other operating expenses	-48,338	-11,543
	-1,303,752	-1,419,843

## Note 17 Financial income

Group	2009	2008
Interest income, miscellaneous	1 342	2 422
Result from short-term investments	8 148	17 745
Exchange rate gains/losses on short term receivables	77	-605
Exchange rate difference long-term liability	12 269	–
Exchange rate difference loan in USD	6 764	–
Other	3	1 856
	28 603	21 418

Parent Company	2009	2008
Interest income, miscellaneous	1 438	2 266
Result from short-term investments	8 148	17 745
Exchange rate gains/losses on short term receivables	86	-756
Exchange rate difference long-term liability	12 269	–
Exchange rate difference loan in USD	6 764	–
Other	–	1 856
	28 705	21 111

## Note 18 Financial expenses

Group	2009	2008
Interest expenses, bank loan	-11,523	–
Interest expenses, miscellaneous	-761	-703
Financing expenses	-221	-476
Other	165	-41
	-12,340	-1,220

Parent Company	2009	2008
Interest expenses, bank loan	-11,523	–
Interest expenses, miscellaneous	-723	-703
Financing expenses	-221	-476
Other	164	-30
	-12,303	-1,209

## Note 19 Exchange rate differences affecting operating profit/loss

Group	2009	2008
Exchange rate differences affecting operating profit/loss	-10,503	4,862
	-10,503	4,862

Parent Company	2009	2008
Exchange rate differences affecting operating profit/loss	-10,517	4,862
	-10,517	4,862

## Note 20 Income tax

### Current tax expense (-)/ tax income (+)

Group	2009	2008
Tax expense / income for the year <sup>1</sup>	–	30,636
Adjustment of taxes related to previous years	–	–
<b>Total tax reported for the Group</b>	<b>–</b>	<b>30,636</b>

Parent Company	2009	2008
Tax income for the year	–	–
Adjustment of taxes related to previous years	–	–
<b>Total tax reported for the Parent Company</b>	<b>–</b>	<b>–</b>

### Reconciliation of actual tax

Group	2009	2008
Pre-tax profit	32,437	-365,997
Tax on the basis of prevailing tax rate for Parent Company	-8,531	102,479
Other non-deductible expenses	-9,205	-11,441
Non-taxable income	1,476	29,886
Decrease (+) / Increase (-) in loss carry-forward without corresponding capitalization of deferred tax	16,261	-90,288
<b>Reported actual tax<sup>1</sup></b>	<b>–</b>	<b>30,636</b>

Parent Company	2009	2008
Pre-tax profit	70,429	-393,043
Tax on the basis of prevailing tax rate for Parent Company	-18,523	110,052
Other non-deductible expenses	-2,116	-3,437
Non-deductible loss on sale of shares in limited partnerships	-1,423	-47,169
Non-taxable income	6,082	29,886
Decrease (+) / Increase (-) in loss carry-forward without corresponding capitalization of deferred tax	15,980	-89,332
<b>Reported actual tax</b>	<b>–</b>	<b>–</b>

Prevailing tax rate for the Parent Company is 26.3 % (28.0%).

<sup>1</sup> 30 550 refers to reversed deferred tax liability and 86 is income tax expense for Paradiset BV

## Note 21 Intangible fixed assets and impairment testing

Group	Goodwill <sup>1</sup>	Research & Development <sup>2</sup>	Trademarks & licences <sup>3</sup>	Product rights <sup>4</sup>	Software and other	IT-software in progress	Total
<b>1 January - 31 December 2008</b>							
Net book value - Opening balance	39,375	297,470	154,865	–	8,722	876	501,308
Start up of plant in progress	–	–	–	–	876	-876	–
Acquisition of subsidiary	25,342	–	–	–	–	–	25,342
Additions	–	–	9,034	690,981	–	–	700,015
Disposals	-34,318	-109,146	-29,828	–	–	–	-173,292
Depreciation	–	–	-631	–	-5,369	–	-6,000
This years translation differences	-5,057	-16,085	-223	–	–	–	-21,365
<b>Net book value - Closing balance</b>	<b>25,342</b>	<b>172,239</b>	<b>133,217</b>	<b>690,981</b>	<b>4,229</b>	<b>–</b>	<b>1,026,008</b>
<b>At December 31, 2008</b>							
Acquisition value	59,660	281,385	165,004	690,981	28,162	–	1,225,192
Accumulated depreciation and amortization	-34,318	-109,146	-31,787	–	-23,933	–	-199,184
<b>Net book value</b>	<b>25,342</b>	<b>172,239</b>	<b>133,217</b>	<b>690,981</b>	<b>4,229</b>	<b>–</b>	<b>1,026,008</b>

**1 January - 31 December 2009**

Net book value - Opening balance	25,342	172,239	133,217	690,981	4,229	–	1,026,008
Additions	–	126,957	14,657	43,740	4,269	–	189,623
Disposals	–	–	-28,317	-4,663	–	–	-32,980
Depreciation	–	–	-1,367	-47,930	-2,527	–	-51,824
Reclassification	–	–	28,317	–	–	–	28,317
<b>Net book value - Closing balance</b>	<b>25,342</b>	<b>299,196</b>	<b>146,507</b>	<b>682,128</b>	<b>5,971</b>	<b>–</b>	<b>1,159,144</b>

**At December 31, 2009**

Acquisition value	59,660	408,342	151,344	730,058	32,431	–	1,381,835
Accumulated depreciation and amortization	-34,318	-109,146	-4,837	-47,930	-26,460	–	-222,691
<b>Net book value</b>	<b>25,342</b>	<b>299,196</b>	<b>146,507</b>	<b>682,128</b>	<b>5,971</b>	<b>–</b>	<b>1,159,144</b>

<sup>1</sup> During 2008, the company submitted an additional purchase sum of SEK 15 million, as well as a shareholders' contribution totalling SEK 10.3 millions regarding Arexis AB.

Furthermore, a write-down of goodwill referring to the primary care project was performed.

<sup>2</sup> During 2008, a write-down of Research and Development regarding primary care projects was performed. Remaining acquired R&D refers to Arexis AB, as well as the investment in certain remaining rights in the research program Leptin, which was sold to Astra Zeneca 2009.

<sup>3</sup> The write-down during 2008 refers to licenses within the primary care project.

<sup>4</sup> Acquired product rights 2008, SEK 690 981 thousands, consists of the products Kineret<sup>®</sup>, Kepivance<sup>®</sup> samt Stemgen<sup>®</sup>

<b>Parent Company</b>	<b>Goodwill</b>	<b>Research &amp; Development<sup>1</sup></b>	<b>Trademarks &amp; licences</b>	<b>Product rights<sup>2</sup></b>	<b>Software and other</b>	<b>IT-software in progress</b>	<b>Total</b>
<b>1 January - 31 December 2008</b>							
Net book value - Opening balance	–	–	151,239	–	8,722	876	160,837
Start up of plant in progress	–	–	–	–	876	-876	–
Additions	–	–	9,034	690,981	–	–	700,015
Disposals	–	–	-28,316	–	–	–	-28,316
Depreciation	–	–	-631	–	-5,369	–	-6,000
<b>Net book value - Closing balance</b>	<b>–</b>	<b>–</b>	<b>131,326</b>	<b>690,981</b>	<b>4,229</b>	<b>–</b>	<b>826,536</b>
<b>At December 31, 2008</b>							
Acquisition value	–	–	160,957	690,981	28,162	–	851,784
Accumulated depreciation and amortization	–	–	-29,631	–	-23,933	–	-25,248
<b>Net book value</b>	<b>–</b>	<b>–</b>	<b>131,326</b>	<b>690,981</b>	<b>4,229</b>	<b>–</b>	<b>826,536</b>
<b>1 January - 31 December 2009</b>							
Net book value - Opening balance	–	–	131,326	690,981	4,229	–	826,536
Additions	–	126,957	14,657	43,740	4,269	–	189,623
Reclassification of acquisition value	–	–	-28,317	-4,663	–	–	-32,980
Depreciation	–	–	-1,367	-47,930	-2,527	–	-51,824
Reclassification of acc depreciations	–	–	28,317	–	–	–	28,317
<b>Net book value - Closing balance</b>	<b>–</b>	<b>126,957</b>	<b>144,616</b>	<b>682,128</b>	<b>5,971</b>	<b>–</b>	<b>959,672</b>
<b>At December 31, 2009</b>							
Acquisition value	–	126,957	147,297	730,058	32,431	–	1,008,427
Accumulated depreciation and amortization	–	–	-2,681	-47,930	-26,460	–	-48,755
<b>Net book value</b>	<b>–</b>	<b>126,957</b>	<b>144,616</b>	<b>682,128</b>	<b>5,971</b>	<b>–</b>	<b>959,672</b>

<sup>1</sup> Investment in certain remaining rights in the research program Leptin, which was sold to Astra Zeneca 2009.

<sup>2</sup> Acquired product rights 2008, SEK 690 981 thousands, consists of the products Kineret<sup>®</sup>, Kepivance<sup>®</sup> samt Stemgen<sup>®</sup>

**Testing for impairment of intangible fixed assets**

Testing for impairment of intangible fixed assets is carried out as needed and done at least once a year. Impairment tests have been carried out for the Group's only segment. A small portion of the Group's reported value relates to goodwill. Impairment tests are based on a calculation of future value in use. Assessments of the value of the Group's goodwill items and other intangible fixed assets are based on the cash generating units' value in use. The value in use is based on cash flows that are expected to be generated over the remaining life of the unit.

The future cash flows used in calculating the various units' value in use are based on a detailed review of the units. The forecast future cash flows for all units have been calculated at present value with a 10 percent discount rate after tax. The discount rate is based on a market assessment of the average cost of capital taking into account the evaluated risk level in the units' cash flow.

*Other assumptions regarding the rate of return:*

Risk free interest rate: 10-year government bond or comparable investment with the lowest possible risk.

Market risk premium: 5 percent

Beta value: Biovitrum's development largely follows the general trend on the market and is therefore calculated as 1.

Interest expense: according to Biovitrum's borrowing costs

Tax rate: According to Swedish tax rates



*Important variables*

Biovitrum is dependent on the success of its research and development projects. Biovitrum has conducted a review of the forecast future cash flows for each of the projects. The cash flow was then adjusted for the probability of the project being commercialized. This rate fluctuates depending on the phase of development of the projects.

*Sensitivity analysis*

Other impairment testing has been performed using a margin in use to fall below the book value. Management is therefore of the opinion that even if there is a certain variation in the most important variables, there will be no write-down requirement.

**Note 22 Tangible fixed assets**

Group	Plant and machinery	Equipment, tools, fixtures and fittings	Plant in progress	Total
<b>1 January - 31 December 2008</b>				
Net book value - Opening balance	109,101	91,050	89,563	289,714
Exchange differences	14,890	70,417	-85,307	—
Additions	6,349	3,025	14,534	23,908
Disposals	-9,627	-168	—	-9,795
Depreciation	-40,051	-23,282	—	-63,333
Write-downs	-7,271	-17,610	—	-24,881
This years translation differences	-96	—	—	-96
Net book value - Closing balance	73,295	123,432	18,790	215,517
<b>At December 31, 2008</b>				
Acquisition value	624,231	241,690	18,790	884,711
Accumulated depreciation and amortization	-550,936	-118,258	—	-669,194
Net book value	73,295	123,432	18,790	215,517
<b>1 January - 31 December 2009</b>				
Net book value - Opening balance	73,295	123,432	18,790	215,517
Exchange differences	1,247	365	-1,612	—
Additions	2,357	4,930	88,794	96,081
Disposals	-3,885	—	—	-3,885
Depreciation	-29,339	-26,411	—	-55,750
Net book value - Closing balance	43,675	102,316	105,972	251,963
<b>At December 31, 2009</b>				
Acquisition value	613,086	246,895	105,972	965,953
Accumulated depreciation and amortization	-569,411	-144,579	—	-713,990
Net book value	43,675	102,316	105,972	251,963
Parent Company	Plant and machinery	Equipment, tools, fixtures and fittings	Plant in progress	Total
<b>1 January - 31 December 2008</b>				
Net book value - Opening balance	102,366	90,619	89,563	282,548
Exchange differences	14,890	70,417	-85,307	—
Additions	6,349	3,025	14,534	23,908
Disposals	-9,627	-168	—	-9,795
Depreciation	-37,855	-22,252	—	-60,107
Write-downs	-7,150	-17,731	—	-24,881
Net book value - Closing balance	68,973	123,910	18,790	211,673
<b>At December 31, 2008</b>				
Acquisition value	615,356	237,614	18,790	871,760
Accumulated depreciation and amortization	-546,383	-113,704	—	-660,087
Net book value	68,973	123,910	18,790	211,673

**1 January - 31 December 2009**

Net book value - Opening balance	68,973	123,910	18,790	211,673
Exchange differences	1,247	365	-1,612	–
Additions	2,357	4,930	88,794	96,081
Disposals	-41	–	–	-41
Depreciation	-29,339	-26,411	–	-55,750
<b>Net book value - Closing balance</b>	<b>43,197</b>	<b>102,794</b>	<b>105,972</b>	<b>251,963</b>

**At December 31, 2009**

Acquisition value	608,055	242,819	105,972	956,846
Accumulated depreciation and amortization	-564,858	-140,025	–	-704,883
<b>Net book value</b>	<b>43,197</b>	<b>102,794</b>	<b>105,972</b>	<b>251,963</b>

**Note 23 Participation in Group companies**

<b>Parent Company</b>	<b>2009</b>	<b>2008</b>
<i>Accumulated acquisition values</i>		
Accumulated acquisition values, opening balance	914 133	878 791
Prepaid expenses acquisition in progress	60 808	–
Acquisitions	–	25 342
Shareholders' contribution	–	10 000
Participation in limited partnerships	-75	–
	<b>974 866</b>	<b>914 133</b>
<i>Accumulated write-down</i>		
Opening balance	-325 887	-157 427
This years write-down	–	-168 460
	<b>-325 887</b>	<b>-325 887</b>
<b>Net book value end of period</b>	<b>648 979</b>	<b>588 246</b>

**Specification of the parent company's and the Group's holdings in Group companies**

<b>Subsidiary / Corp Identity No / Domicile</b>	<b>No of shares</b>	<b>Share in % <sup>1</sup></b>	<b>Book value</b>
Biovitrum Treasury AB, 556616-7317, Stockholm, Sweden	1,000	100.0	100
Paradisat B.V., 34209249, Amsterdam, Netherlands	180	100.0	164
Fastighetsaktiebolaget Paradiset, 556149-2611, Stockholm, Sweden	900	90.0	90
Hornet Fastighetsbolag KB, 916613-5534, Stockholm, Sweden	1	1.0	–
Fastighetsbolaget Paradiset KB, 916400-9350, Stockholm, Sweden	1	1.0	–
Hornet Fastighetsbolag KB, 916613-5534, Stockholm, Sweden	1	99.0	381,372
Fastighetsbolaget Paradiset KB, 916400-9350, Stockholm, Sweden	1	99.0	36,140
Nya Paradiset 19 AB, 556603-1943, Stockholm, Sweden	1,000	100.0	100
Fastighetsaktiebolaget Paradiset, 556149-2611, Stockholm, Sweden	100	10.0	–
Arexis AB, 556573-5130, Gothenburg, Sweden	1,000	100.0	170,205
Arexis Infram AB, 556584-4676, Gothenburg, Sweden	1,000	100.0	–
Prepaid expenses acquisition in progress	–	–	60,808
			<b>648,979</b>

<sup>1</sup> Refers to the percentage of capital holding, which is equal to the percentage of voting rights.

## Note 24 Financial fixed assets

Group	2009	2008
<i>Accumulated acquisition values</i>		
Opening balance	34,426	17,443
Acquisition <sup>1</sup>	60,830	–
Loan	1,883	12,021
Reclaimed deposition	-34	–
Change in pension commitment	5,598	4,962
Other	4	–
<b>Accumulated acquisition values</b>	<b>102,707</b>	<b>34,426</b>
<b>Book value at end of period</b>	<b>102,707</b>	<b>34,426</b>

<sup>1</sup> Prepaid expenses acquisition in progress

Parent Company	2009	2008
<i>Accumulated acquisition values</i>		
Opening balance	19,489	7,468
Acquisition	21	–
Loan	1,883	12,021
Return of deposit	-34	–
<b>Accumulated acquisition values</b>	<b>21,359</b>	<b>19,489</b>
<b>Book value at end of period</b>	<b>21,359</b>	<b>19,489</b>

## Note 25 Derivative instruments

Group	2009		2008	
	Assets	Liabilities	Assets	Liabilities
Hedging cash flow	–	–	–	3,260
<b>Accumulated acquisition values</b>	<b>–</b>	<b>–</b>	<b>–</b>	<b>3,260</b>

Parent Company	2009		2008	
	Assets	Liabilities	Assets	Liabilities
Hedging cash flow	–	–	–	3,260
<b>Accumulated acquisition values</b>	<b>–</b>	<b>–</b>	<b>–</b>	<b>3,260</b>

## Currency forward contracts

The nominal amount of outstanding currency forward contracts as of December 31, 2009 was SEK 0 thousands (12,265). All contracts as of December 31, 2008 had a remaining term of less than twelve months.

## Note 26 Deferred tax assets and liabilities

### Reported deferred tax assets receivables and liabilities

Group 2009	Deferred tax receivable	Deferred tax liability	Net
Acquired R&D	–	-45,273	45,273
Deferred pension expense	–	-5,598	5,598
Loss carry-forward	14,471	–	14,471
	<b>14,471</b>	<b>-50,871</b>	<b>-36,400</b>
Offsetting	-5,598	5,598	–
<b>Net deferred tax receivable/liability</b>	<b>8,873</b>	<b>-45,273</b>	<b>-36,400</b>

Group 2008	Deferred tax receivable	Deferred tax liability	Net
Acquired R&D	–	-45,273	45,273
Deferred pension expense	–	-3,928	3,928
Loss carry-forward	12,801	–	12,801
	<b>12,801</b>	<b>-49,201</b>	<b>-36,400</b>
Offsetting	-3,928	3,928	–
<b>Net deferred tax receivable/liability</b>	<b>8,873</b>	<b>-45,273</b>	<b>-36,400</b>

For the Parent Company there is no deferred tax receivable or tax liability.

### Deferred tax receivables and liabilities not reported

Group	2009-12-31	2008-12-31
Deficit for tax purpose	258,854	292,520
	<b>258,854</b>	<b>292,520</b>

Parent Company	2009-12-31	2008-12-31
Deficit for tax purpose	198,158	227,981
	<b>198,158</b>	<b>227,981</b>

The loss carry-forwards for tax purposes pertain to the parent company and a Swedish subsidiary. According to tax legislation, this deficit can be carried forward indefinitely. Deferred tax receivables will be reported for the above items when it is deemed likely that the Group will be able to utilize the amounts to offset future taxable profits. Tax rate used is 26.3 percent as per 2009 (28.0).

Following a tax audit, the amounts from last year have been changed.

### Change in deferred tax in temporary differences and loss carry-forward

	Amount January, 1	Reported in income statement	Acquired R&D	Difference in currency rate reported against equity	Amount December, 31
<b>Group 2009</b>					
Acquired R&D	-45,273	–	–	–	-45,273
Deferred pension expense	-3,928	-1,670	–	–	-5,598
Utilization of loss carry-forward	12,801	1,670	–	–	14,471
	<b>-36,400</b>	<b>–</b>	<b>–</b>	<b>–</b>	<b>-36,400</b>

	Amount January, 1	Reported in income statement	Acquired R&D	Difference in currency rate reported against equity	Amount December, 31
<b>Group 2008</b>					
Acquired R&D	-83,252	30,550	2,927	4,502	-45,273
Deferred pension expense	-2,793	-1,135	–	–	-3,928
Utilization of loss carry-forward	14,593	1,135	-2,927	–	12,801
	<b>-71,452</b>	<b>30,550</b>	<b>–</b>	<b>4,502</b>	<b>-36,400</b>

### Note 27 Inventories

Group	2009	2008
Raw materials and consumables	9,149	8,739
Work-in-progress	396,957	470,455
Finished products and goods for resale	172,292	108,469
	<b>578,398</b>	<b>587,663</b>

Parent Company	2009	2008
Raw materials and consumables	9,149	8,739
Work-in-progress	396,957	470,455
Finished products and goods for resale	172,292	108,469
	<b>578,398</b>	<b>587,663</b>

The expenditure for inventories that was carried as an expense is included in cost of goods sold and amounted to SEK 134,387 thousands (63,607).

Provision for obsolescence amounts to SEK 6,922 thousands (42,592).

## Note 28 Accounts receivable and other receivables

Group	2009	2008
Accounts receivable	106,539	75,035
Deduction: Provision for decrease in receivable	-1,336	–
Accounts receivable - net	105,203	75,035
Tax receivables	26,572	17,182
Other receivables	6,537	16,478
Total other receivables	33,109	33,660
<b>Total accounts receivable and other receivables</b>	<b>138,312</b>	<b>108,695</b>
Parent Company	2009	2008
Accounts receivable	106,539	75,036
Deduction: Provision for decrease in receivable	-1,336	–
Accounts receivable - net	105,203	75,036
Tax receivables	16,858	17,182
Other receivables	6,336	15,529
Total other receivables	23,194	32,711
<b>Total accounts receivable and other receivables</b>	<b>128,397</b>	<b>107,747</b>

There have been no write-downs that have impacted the income statement.

As of December 31, 2009, accounts receivable amounting to SEK 25,639 thousands (9,193) were past due and no write-down was deemed necessary. SEK 11,055 thousands of the past due accounts receivable as of December 31, 2009 were settled in January 2010. Provisions for doubtful receivables amounted to SEK 1,336 thousands as of December 31, 2009.

### Accounts receivable past due

Group and Parent Company	2009	2008
Past due 1-30 days	10,974	3,707
Past due 31-90 days	6,631	5,486
Past due 91-180 days	5,472	–
Past due > 181 days	2,562	–
	25,639	9,193

### Amounts, per currency, for accounts receivable and other receivables

Group	2009	2008
SEK	43,738	75,075
NOK	1,936	313
DKK	1,129	216
USD	32,595	15,497
EUR	52,951	13,910
GBP	2,927	1,175
CHF	199	192
AUD	1,128	2,317
Other currencies	1,709	–
	138,312	108,695
Parent Company	2009	2008
SEK	33,823	74,869
NOK	1,936	313
DKK	1,129	216
USD	32,595	15,497
EUR	52,951	13,910
GBP	2,927	433
CHF	199	192
AUD	1,128	2,317
Other currencies	1,709	–
	128,397	107,747

## Note 29 Prepaid expenses and accrued income

Group	2009	2008
Accrued royalty revenues	36,784	44,869
Accrued co-promotion revenues	33,769	41,106
Accrued revenues product sales	1,136	–
Accrued interest income	363	4,966
Prepaid leasing fees	1,651	1,701
Prepaid rents	14,113	20,927
Prepaid insurance expenses	11,714	9,154
Prepaid service and maintainance expenses	733	4,718
Prepaid IT Software & Licenses	3,247	2,894
Prepaid issuing costs	84,400	–
Advance, raw material production of Kineret	31,999	–
Receivable on BiogenIddec, expenses during 2009 related to project FIX and FVIII	26,084	–
Other items	10,574	4,310
	256,567	134,645

Parent Company	2009	2008
Accrued royalty revenues	36,784	44,869
Accrued co-promotion revenues	33,769	41,106
Accrued revenues product sales	1,136	–
Accrued interest income	363	4,966
Prepaid leasing fees	1,651	1,701
Prepaid rents	14,113	18,654
Prepaid insurance expenses	11,714	9,154
Prepaid service and maintainance expenses	733	4,718
Prepaid IT Software & Licenses	3,247	2,894
Prepaid issuing costs	84,400	–
Advance, raw material production of Kineret	31,999	–
Receivable on BiogenIddec, expenses during 2009 related to project FIX and FVIII	26,084	–
Other items	10,574	4,310
	256,567	132,372

## Note 30 Current assets

There are no receivables maturing later than one year from the balance sheet date.

## Note 31 Short-term investments, cash and cash equivalents

### Specification of securities

Group	2009		2008	
	Fair value	Book value	Fair value	Book value
<i>Short-term investments</i>				
Discount securities	–	–	21,925	21,925
Coupon securities	48,359	48,359	183,908	183,908
	48,359	48,359	205,833	205,833
<i>Liquid funds</i>				
Interest rate funds	123,687	123,687	60,607	60,607
Short term investments equivalent to liquid funds	5,000	5,000	–	–
Cash and Bank	129,593	129,593	193,621	193,621
	258,280	258,280	254,228	254,228

Parent Company	2009		2008	
	Fair value	Book value	Fair value	Book value
<i>Short-term investments</i>				
Discount securities	–	–	21,925	21,925
Coupon securities	48,359	48,359	183,908	183,908
	48,359	48,359	205,833	205,833
<i>Liquid funds</i>				
Interest rate funds	123,687	123,687	60,607	60,607
Short term investments equivalent to liquid funds	5,000	5,000	–	–
Cash and Bank	129,290	129,290	191,643	191,643
	257,977	257,977	252,250	252,250

### Note 32 Financial assets by category (group)

	Loans and receivables	Asset at fair value through the profit and loss	Derivatives used for hedging	Available for sale	Total
<b>December 31, 2009</b>					
<b>Assets as per balance sheet</b>					
Accounts receivable	105,203	–	–	–	105,203
Short-term investments	–	48,359	–	–	48,359
Liquid funds	258,280	–	–	–	258,280
<b>Total</b>	<b>363,483</b>	<b>48,359</b>	<b>–</b>	<b>–</b>	<b>411,842</b>
	Loans and receivables	Asset at fair value through the profit and loss	Derivatives used for hedging	Available for sale	Total
<b>December 31, 2008</b>					
<b>Assets as per balance sheet</b>					
Accounts receivable	75,036	–	–	–	75,036
Short-term investments	–	205,833	–	–	205,833
Liquid funds	254,228	–	–	–	254,228
<b>Total</b>	<b>329,264</b>	<b>205,833</b>	<b>–</b>	<b>–</b>	<b>535,097</b>

### Note 33 Post-employment benefits

The pension commitments are calculated annually on the balance sheet date, based on actuarial calculations.

The figures below do not include a special payroll tax of 24.26 percent of reported assets in accordance with UFR4 (statement from Swedish Financial Reporting Board).

Pension costs are reported under the items: selling expenses, administrative expenses and research and development expenses.

#### Pension benefits

Commitments for retirement pensions and family pensions for white-collar employees in Sweden are insured through Alecta. According to statement UFR3 issued by the Swedish Financial Reporting Board, these are defined benefit plans covering multiple employers.

For the 2009 financial year, the group did not have access to the information necessary to be able to report this plan as a defined benefit plan. The ITP pension plan insured through Alecta is therefore reported as a defined contribution plan.

The cost for the year of pension insurance through Alecta amounted to SEK 20,459 thousands (14,592). Alecta's surplus is distributable among the policy holders and/or the insured parties. At the end of 2009 Alecta's surplus in the form of the collective consolidation level amounted to SEK 141.0 percent (112.0). The collective consolidation level consists of the market value of Alecta's assets as a percentage of insurance commitments calculated according to Alecta's actuarial calculation assumptions, which do not correspond to IAS 19.

**Change in the defined benefit obligation:**

	2009	2008
Benefit obligation at start of year	106,541	86,154
Service cost	15,112	14,345
Interest cost	3,446	3,846
Actuarial gains (-) / losses (+)	8,857	11,110
Benefits paid	-120	-27,138
Collective agreement pension	12,100	18,224
Remunerations	-38,211	-
<b>Benefit obligation at end of year</b>	<b>107,725</b>	<b>106,541</b>

**Change in fair value of plan assets during the year:**

	2009	2008
Fair value of plan assets at start of year	97,432	86,199
Return on assets	4,189	4,259
Actuarial gain (+) / loss (-)	-2,173	-2,116
Contributions	35,434	36,228
Remunerations	-38,211	-27,138
Remunerations one-time items	-1,890	-
<b>Fair value of plan assets at end of year</b>	<b>94,781</b>	<b>97,432</b>

**The amounts recognized in the income statement are as follows:**

	2009	2008
Service cost	15,112	14,344
Interest cost	3,446	3,846
Expected return on plan assets	-4,189	-4,259
Amortization on actuarial gains/losses	2,691	78
Collective agreement pension	12,100	18,224
<b>Total, included in employee benefits</b>	<b>29,160</b>	<b>32,233</b>

**Actuarial assumptions on the balance sheet date**

	2009	2008
Discount rate	3.90%	4.00%
Future salary increases	3.00%	3.00%
Future pension increases	2.00%	2.00%
Expected increase of basic amount	3.00%	2.50%
Expected return on plan assets	3.30%	4.00%

**The amounts recognized in the balance sheet were determined as follows:**

	2009	2008
Fair value of plan assets	94,781	97,432
Fair value pension commitment	-107,725	-106,541
<b>Net asset value</b>	<b>-12,944</b>	<b>-9,109</b>
Unrecognized actuarial gains (-) / losses (+)	29,470	21,131
<b>Net asset value</b>	<b>16,526</b>	<b>12,022</b>

**Specification of changes in net assets reported in the balance sheet**

	2009	2008
Net asset/liability at beginning of year according adopted balance sheet	12,022	8,027
Net pension expense	-29,160	-32,233
Benefits paid	35,434	36,228
Withdrawal from plan assets (-)	-1,890	-
Remunerations	-	-27,138
Benefits paid	120	27,138
<b>Net asset value</b>	<b>16,526</b>	<b>12,022</b>

The actual return on plan assets was SEK 2,016 thousands (2,143).

**Specification of asset type**

	2009	%	2008	%
Shares	41,704	44	6,311	7
Bonds	42,651	45	8,771	9
Other	10,426	11	3,334	3
Insurance company provision	0	0	79,016	81
<b>Total</b>	<b>94,781</b>	<b>100</b>	<b>97,432</b>	<b>100</b>

**Other information**

The anticipated return on plan assets is established by taking into account the anticipated return on the assets that are covered by the investment policy in question. The anticipated return on investments with fixed interest is based on the return received if these securities are held to maturity. The anticipated return on shares is based on the long-term return in the respective market.

Contributions made to plans for remuneration after terminated employment is expected to amount to SEK 13,205 thousands.



As per December 31	2009	2008	2007	2006	2005
Present value of defined benefit obligation	-107,725	-106,541	-86,154	-87,154	-67,040
Fair value of plan assets	94,781	97,432	86,199	69,534	52,985
<b>Surplus/(Deficit)</b>	<b>-12,944</b>	<b>-9,109</b>	<b>45</b>	<b>-17,620</b>	<b>-14,055</b>
Experience adjustments on plan liabilities, gain (-) / loss (+)	11,170	1,030	-808	12,283	3,338
Change in assumptions of plan liabilities, gain (-) / loss (+)	-2,312	10,080	-8,118	-	-
Experience adjustments on plan assets, gain (+) / loss (-)	-2,173	-2,116	2,697	3,139	1,695

### Note 34 Other liabilities, long-term

Group	2009	2008
Liabilities to credit institutions (in USD)	200,000	300,000
Liabilities to credit institutions (in SEK)	90,348	97,113
	290,348	397,113
Parent company	2009	2008
Liabilities to credit institutions (in USD)	200,000	300,000
Liabilities to credit institutions (in SEK)	90,348	97,113
	290,348	397,113

In connection with the company's acquisition of the drugs Kepivance<sup>®</sup> and Stemgen<sup>®</sup> and the exclusive licensing agreement for Kineret<sup>®</sup>, at the end of 2008 the company took two long-term loans to finance the transactions. One loan of SEK 300 M is in Swedish kronor and one loan equivalent to SEK 100 M is in USD.

The company's entire borrowing in USD is in the form of a seven-year loan, with set installments, of USD 6,263,309 and a revolving credit facility of USD 6,263,309. Security for the bank loan consists of future royalty revenues from ReFacto<sup>®</sup>. The interest on the loan is according to STIBOR or the corresponding reference interest rate +1.75 percent until June 16, 2009 and thereafter +1.3 percent. When these loans were taken, the company made a commitment to the bank regarding the equity/assets ratio and accumulated cash flows in 2008 – 2009 and annual cash flows from 2010 onwards.

### Note 35 Other provisions

	Group 2009-12-31	2008-12-31	Parent Company 2009-12-31	2008-12-31
Opening balance	477,231	5,931	477,231	-
Costs incurred	-92,242	-3,710	-92,242	-
Currency exchange difference	-12,260	-	-12,260	-
Provision this year	-	475,010	-	477,231
Closing balance	372,729	477,231	372,729	477,231

SEK 365,645 thousands is milestone payments (USD 60 M). The remaining SEK 7,084 thousands relates to restructuring costs for rents and employees. Milestones are expected to fall due for payment between the 2011 and 2015, see the table on page 49. See note 39 "Significant events after the balance sheet date" regarding agreement on prepayment of future milestone remunerations.

	Group 2009-12-31	2008-12-31	Parent Company 2009-12-31	2008-12-31
Long-term	365,645	377,905	365,645	377,905
Short-term	7,084	99,326	7,084	99,326
Total provisions	372,729	477,231	372,729	477,231

### Restructuring expenses

No restructuring was carried out in 2009.

### Note 36 Accrued expenses and deferred income

Group	2009	2008
Provision for vacation pay and bonus incl social security contributions	60,735	71,020
Accrued social security contributions	26,520	21,468
Accrued expenses	93,192	73,890
Prepaid revenues	423	43,606
Accrued expenses acquisition in progress	45,000	–
Accrued expenses new share issue	79,357	–
Accrued expenses sale of subsidiary	4,994	–
Other items	–	1,584
	310,221	211,568

Parent Company	2009	2008
Provision for vacation pay and bonus incl social security contributions	60,735	71,020
Accrued social security contributions	26,520	21,468
Accrued expenses	97,045	77,706
Prepaid revenues	423	43,606
Accrued expenses acquisition in progress	45,000	–
Accrued expenses new share issue	79,357	–
Accrued expenses sale of subsidiary	4,994	–
Other items	–	1,584
	314,074	215,384

### Note 37 Pledged assets and contingent liabilities

Parent Company	2009	2008
Contingent liabilities	–	–
Bank guarantee	78,444	40,654

### Note 38 Transactions with related parties

#### Loans to related parties

	2009	2008
Loan to executive management in Parent Company:	–	–
At beginning of the year:	153	153
Loan paid during the year	–	–
	153	153

The following terms and conditions apply to the loans issued to senior executives:

- The loans are interest free. A benefit is assigned to the borrower annually corresponding to the borrowed amount multiplied by the government loan interest plus one percentage point per year, which is in line with the rules in the Income Tax Act for valuation of loans in Swedish currency with an interest rate that is fixed in relation to the market interest rate or interest free loans. The benefit is measured on the date the loan is taken and updated annually.
- The borrowers agree to repay the entire borrowed amount to the lender, or for endorsement, the first of the following occasions:
  - the day the borrower resigns his/her position within the Biovitrum Group
  - May 31, 2011, when the warrants expire
  - the day the borrower receives the issued shares as a result of the borrower converting all warrants into shares.

#### Other

Biovitrum has entered into a collaboration agreement with Affibody AB. Håkan Åström is chairman of the board in Biovitrum as well as in Affibody AB.

### Note 39 Significant events after the balance sheet date

- On November 5, 2009 Biovitrum announced its acquisition of Swedish Orphan. The transaction was concluded in January 14, 2010 and was financed through a rights issue, an issue in kind and bank loans.
- Biovitrum and Biogen Idec have constructed a partnership agreement for the companies' long-acting recombinant factor VIII Fc and factor IX Fc fusion protein for the treatment of hemophilia A and hemophilia B

respectively. Under the agreement Biogen Idec will take primary responsibility for development and will cover the costs of the FIX and FVIII projects.

- Biovitrum and Biogen Idec have recruited the first patients for an open-label registrational trial that will be conducted at several clinical centers. The trial has been designed to analyze the efficacy, pharmacokinetics and safety of the long-acting protein rFIXFc in hemophilia B patients (the B-LONG trial).
- A contract were signed with Amgen regarding an additional Kineret<sup>®</sup> bulk drug campaign to meet an expected increased market demand of Kineret<sup>®</sup> until Biovitrum has transferred manufacturing processes to new contract manufacturers. In addition, Biovitrum will pay to buy-out previously agreed future sales milestones for Kineret<sup>®</sup> and Kepivance<sup>®</sup>. The milestones amounts to a total nominal value of USD 60 M. Present value as per balance sheet date for these milestones are USD 51 M.

The Board of Directors and the CEO of Biovitrum certify that the consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (IFRS) as adopted by the EU and provide a fair and true description of the Group's financial position and results.

The Directors' Report for the Group and the parent company gives a fair and true description of the development of the Group's and the parent company's operations, financial position and results, and describes significant risks and uncertainties that the parent company and the companies in the Group are facing.

The Income Statements and Balance Sheets will be presented for adoption at the Annual General Meeting on April 27, 2010.

Stockholm, March 19, 2010

Håkan Åström  
Chairman

Hans Glemstedt

Mats-Olof Ljungkvist

Michael Steinmetz

Wenche Rolfsen

Peter Sellei

Hans Wigzell

Catarina Larsson  
Employee representative

Bo-Gunnar Rosenbrand  
Employee representative

Martin Nicklasson  
CEO

Our audit report was submitted on March 19, 2010

PricewaterhouseCoopers AB  
Mikael Winkvist  
Authorized Public Accountant

## **Board of Directors**

### **Håkan Åström, chairman**

Born 1947. M.Sc. in Business Administration and Economics. Med. Dr. h.c. Sahlgrenska Academy, Gothenburg University 2003. Board member since 2001, chairman of the board since 2004. Board member of Karolinska Institutet, Ferrosan AS (chairman), Orexo AB (chairman), Rehnman och Partners, SANOS AS (chairman) och Topotarget AS (chairman). Former CEO Kabi Pharmacia and Senior Vice President Pharmacia Corporation.

Shares: 150 000  
Warrants: 0

### **Hans Glemstedt**

Born 1962. M.Sc. Business Administration and Economics. Team member in the Operating Investment group at Investor since 2006. Previously senior manager at McKinsey during 9 years. More than 10 years of private equity and venture capital investments experience.

Shares: 6 000  
Warrants: 0

### **Mats-Olof Ljungkvist**

Born 1951. B.Sc. in Economics and Business Administration. Board member since 2007. Senior Advisor, Atos Consulting AB. Board member of HL Display AB, SBC BostadsrättsCentrum AB, Catella Capital AB, Amplion AB, Swedsec AB, Swegro AB, Hermods AB (chairman) and Twentyfourseven AB (chairman). Former CFO in Carnegie & Co, CEO in Aragon and CFO in Apoteksbolaget.

Shares: 6 000  
Warrants: 0

### **Wenche Rolfsen**

Born 1952. Pharm. Dr. Professor Pharmaceutical Faculty, Uppsala University. Board member since 2004. Currently board member of Aprea (chairman), Denator (chairman), Artimplant, Industrifonden and Aker Biomarine AS, Norge. Previously held senior management positions at PharmaciaUpjohn, CEO at Quintiles AB and Vice President Quintiles Europe, Explorative Clinical Research.

Shares: 33 400  
Warrants: 0

### **Peter Sellei**

Born 1960. M.D. Karolinska Institutet 1987. US medical degree in 1989. Pursued experimental research in cooperation with Astra-Hässle. Board member since 2009. Head of Healthcare Sector in the Core Investment Department at Investor AB. Deputy member of the board of Neuronova. Previously thoracic and cardiac surgeon at Karolinska Hospital and pharmaceutical analyst at Carnegie Investment Bank.

Shares: 0  
Warrants: 0

### **Michael Steinmetz**

Born 1947. Ph.D. Board member since 2001. Managing Director Clarus Ventures LLC. Board member of Allozyne (Chairman), CGI Pharmaceuticals, Delenex AB, Heptares, MacroGenics, Oxford Immunotec, TaiGen (Chairman), Virdante (Chairman) and VLST. Previously General Partner MPM Capitals Funds Bio Ventures I, II and III.

Shares: 0  
Warrants: 0

### **Hans Wigzell**

Born 1938. MD, Ph. D. Professor Immunology. Board member since 2004. Chairman of Biovitrum Scientific Advisory Board since 2001. Member of the Royal Swedish Academy of Sciences and the Royal Swedish Academy of Engineering Sciences. President of Karolinska Institutet 1995-2003. Member of the Board of the Karolinska Development AB (Chairman) RaySearch AB, Probi AB, Intercell AG and Neodynamics.

Shares: 180 000  
Warrants: 0

### *Union representatives:*

#### **Catarina Larsson**

Born 1952. Laboratory engineer. Board member since 2001. Representative of Federation of Salaried Employees in Industry and Services.

Shares: 600  
Warrants: 0

#### **Bo-Gunnar Rosenbrand**

Born 1963. Laboratory engineer. Deputy board member since 2001. Board member since 2006. Representative of Federation of Salaried Employees in Industry and Services.

Shares: 1 050  
Warrants: 0

## **Audit report**

### **To the annual meeting of the shareholders of**

## **Biovitrum AB (publ)**

Corporate identity number 556038-9321

We have audited the annual accounts, the consolidated accounts, the accounting records and the administration of the board of directors and the managing director of Biovitrum AB (publ) for the year 2009. The board of directors and the managing director are responsible for these accounts and the administration of the company as well as for the application of the Annual Accounts Act when preparing the annual accounts and the application of international financial reporting standards IFRSs as adopted by the EU and the Annual Accounts Act when preparing the consolidated accounts. Our responsibility is to express an opinion on the annual accounts, the consolidated accounts and the administration based on our audit.

We conducted our audit in accordance with generally accepted auditing standards in Sweden. Those standards require that we plan and perform the audit to obtain reasonable assurance that the annual accounts and the consolidated accounts are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the accounts. An audit also includes assessing the accounting principles used and their application by the board of directors and the managing director and significant estimates made by the board of directors and the managing director when preparing the annual accounts and consolidated accounts as well as evaluating the overall presentation of information in the annual accounts and the consolidated accounts. As a basis for my (our) opinion concerning discharge from liability, we examined significant decisions, actions taken and circumstances of the company in order to be able to determine the liability, if any, to the company of any board member or the managing director. We also examined whether any board member or the managing director has, in any other way, acted in contravention of the Companies Act, the Annual Accounts Act or the Articles of Association. We believe that our audit provides a reasonable basis for our opinion set out below.

The annual accounts have been prepared in accordance with the Annual Accounts Act and give a true and fair view of the company's financial position and results of operations in accordance with generally accepted accounting principles in Sweden. The consolidated accounts have been prepared in accordance with international financial reporting standards IFRSs as adopted by the EU and the Annual Accounts Act and give a true and fair view of the group's financial position and results of operations. The statutory administration report is consistent with the other parts of the annual accounts and the consolidated accounts.

We recommend to the annual meeting of shareholders that the income statement for the parent company, the consolidated statement of comprehensive income and balance sheets of the parent company and the group be adopted, that the profit of the parent company be dealt with in accordance with the proposal in the administration report and that the members of the board of directors and the managing director be discharged from liability for the financial year.

Stockholm March 19, 2010

PricewaterhouseCoopers AB

Mikael Winkvist.  
Authorized Public Accountant